EXHIBIT A-1

CT Corporation

Service of Process Transmittal

04/13/2022
CT Log Number 541400844

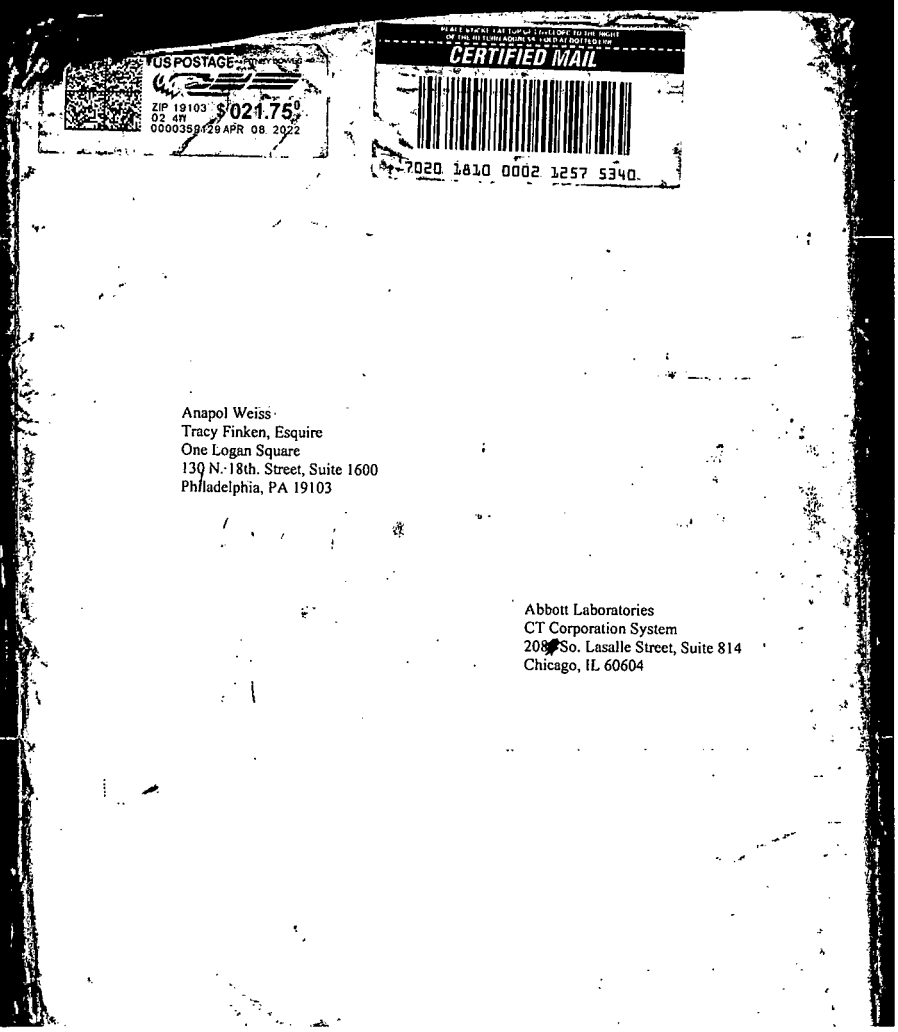
TO: Lauren Groblewski
Abbott Laboratories
100 ABBOTT PARK RD
NORTH CHICAGO, IL 60064-3502

RE: **Process Served in Illinois**

FOR: Abbott Laboratories (Domestic State: IL)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Re: Terraine Abdullah, on Her Own Behalf and as Parent and Natural Guardian of H.S., a Minor // To: Abbott Laboratories
DOCUMENT(S) SERVED:	-
COURT/AGENCY:	None Specified Case # 220302583
NATURE OF ACTION:	Product Liability Litigation - Manufacturing Defect
ON WHOM PROCESS WAS SERVED:	C T Corporation System, Chicago, IL
DATE AND HOUR OF SERVICE:	By Certified Mail on 04/13/2022 postmarked on 04/08/2022
JURISDICTION SERVED :	Illinois
APPEARANCE OR ANSWER DUE:	None Specified
ATTORNEY(S) / SENDER(S):	None Specified
ACTION ITEMS:	CT has retained the current log, Retain Date: 04/14/2022, Expected Purge Date: 04/19/2022 Image SOP Email Notification, Lauren Groblewski lauren.lucy@abbott.com Email Notification, Jennifer Curtis jennifer.curtis@abbott.com
REGISTERED AGENT ADDRESS:	C T Corporation System 208 South LaSalle Street Suite 814 Chicago, IL 60604 877-564-7529 MajorAccountTeam2@wolterskluwer.com



Anapol Weiss
Tracy Finken, Esquire
One Logan Square
130 N. 18th. Street, Suite 1600
Philadelphia, PA 19103

Abbott Laboratories
CT Corporation System
208 So. Lasalle Street, Suite 814
Chicago, IL 60604

ANAPOLWEISS

Tracy A. Finken, Esquire
One Logan Square
130 N. 18th Street, Suite 1600
Philadelphia PA 19103
tfinken@anapolweiss.com

(215) 735-0773 Direct Dial
(215) 875-7731 Direct Fax

April 8, 2022

Abbott Laboratories
CT Corporation System
2089 So. Lasalle Street, Suite 814
Chicago, IL 60604

Re: Service of Summons and Complaints

Dear Sir/Madam:

Enclosed please find a true and correct copy of the following Plaintiffs' Summons and Complaints, the originals of which were filed of record in the Philadelphia Court of Common Pleas on March 24, 2022, relative to the above-captioned matter:

1. Terraine Abdullah, et al. v. Mead Johnson Company, et al., Civil Action No. 220302583;
2. Holli Carter, et al. v. Mead Johnson Company, et al., Civil Action No. 220302588;
3. Shondera Drayton, et al . v. Mead Johnson Company, et al., Civil Action No. 220302594;
4. Alice Stills, et al. v. Mead Johnson Company, et al., Civil Action No.220302617;
5. Christina Taylor, et al. v. Mead Johnson Company, et al., Civil Action No.220302606;
6. Gina Wieger, et al. v. Mead Johnson Company, et al., Civil Action No. 220302614;
7. Gina Wieger, et al, v. Mead Johnson Company, et al., Civil Action No. 220302601

Plaintiff shall deem this case served upon your receipt of the enclosed Summons and Complaints. Please respond to the enclosed pursuant to the allotted time required under Pennsylvania law.

Very truly yours,

TRACY A. FINKEN

TAF/nsg
Enclosures
Via Certified Mail/Return Receipt Requested: 7020 1810 0002 1257 5340

Court of Common Pleas of Philadelphia County
Trial Division

Civil Cover Sheet

For Prothonotary Use Only (Docket Number)
MARCH 2022 002583
E-Filing Number: 2203054444

PLAINTIFF'S NAME TERRAINE ABDULLAH	DEFENDANT'S NAME MEAD JOHNSON & COMPANY, LLC,
PLAINTIFF'S ADDRESS 335 PASSMORE STREET PHILADELPHIA PA 19111	DEFENDANT'S ADDRESS ILLINOIS CORPORATION SERVICE C 801 ADLAI STEVENSON DRIVE SPRINGFIELD IL 62703
PLAINTIFF'S NAME H S	DEFENDANT'S NAME MEAD JOHNSON NUTRITION COMPANY
PLAINTIFF'S ADDRESS 335 PASSMORE STREET PHILADELPHIA PA 19111	DEFENDANT'S ADDRESS ILLINOIS CORPORATION SERVICE C 801 ADLAI STEVENSON DRIVE SPRINGFIELD IL 62703
PLAINTIFF'S NAME	DEFENDANT'S NAME ABBOTT LABORATORIES
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS CT CORPORATION SYSTEM 208 SO. LASSALLE STREET SUITE 814 CHICAGO IL 60604

TOTAL NUMBER OF PLAINTIFFS	TOTAL NUMBER OF DEFENDANTS	COMMENCEMENT OF ACTION
2	5	☒ Complaint ☐ Petition Action ☐ Notice of Appeal ☐ Writ of Summons ☐ Transfer From Other Jurisdictions

AMOUNT IN CONTROVERSY
☐ $50,000.00 or less
☒ More than $50,000.00

COURT PROGRAMS
☐ Arbitration ☐ Mass Tort ☐ Commerce ☐ Settlement
☒ Jury ☐ Savings Action ☐ Minor Court Appeal ☐ Minors
☐ Non-Jury ☐ Petition ☐ Statutory Appeals ☐ W/D/Survival
☐ Other:

CASE TYPE AND CODE
2P - PRODUCT LIABILITY

STATUTORY BASIS FOR CAUSE OF ACTION

FILED
PRO PROTHY
MAR 24 2022
S. RICE

RELATED PENDING CASES (LIST BY CASE CAPTION AND DOCKET NUMBER)

IS CASE SUBJECT TO COORDINATION ORDER?
YES NO

TO THE PROTHONOTARY:

Kindly enter my appearance on behalf of Plaintiff/Petitioner/Appellant: TERRAINE ABDULLAH , H S

Papers may be served at the address set forth below.

NAME OF PLAINTIFF'S/PETITIONER'S/APPELLANT'S ATTORNEY TRACY A. FINKEN	ADDRESS ONE LOGAN SQUARE 130 N. 18TH ST. SUITE 1600 PHILADELPHIA PA 19103
PHONE NUMBER (215)735-0773 FAX NUMBER (215)875-7731	
SUPREME COURT IDENTIFICATION NO. 82258	E-MAIL ADDRESS tfinken@anapolweiss.com
SIGNATURE OF FILING ATTORNEY OR PARTY *TRACY FINKEN*	DATE SUBMITTED Thursday, March 24, 2022, 01:57 pm

FINAL COPY (Approved by the Prothonotary Clerk)

COMPLETE LIST OF DEFENDANTS:

1. MEAD JOHNSON & COMPANY, LLC,
   ILLINOIS CORPORATION SERVICE C 801 ADLAI STEVENSON DRIVE
   SPRINGFIELD IL 62703
2. MEAD JOHNSON NUTRITION COMPANY
   ILLINOIS CORPORATION SERVICE C 801 ADLAI STEVENSON DRIVE
   SPRINGFIELD IL 62703
3. ABBOTT LABORATORIES
   CT CORPORATION SYSTEM 208 SO. LASSALLE STREET SUITE 814
   CHICAGO IL 60604
4. THE PA HOSPITAL OF THE UNIVERSITY OF PA HEALTH SYSTEM
   ALIAS: PENNSYLVANIA HOSPITAL
   3400 CIVIC CENTER BLVD
   PHILADELPHIA PA 19104
5. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA
   ALIAS: PENN MEDICINE
   133 SOUTH 36TH STREET
   PHILADELPHIA PA 19104

ANAPOL WEISS
BY: TRACY FINKEN, ESQUIRE
Identification Number: 82258
One Logan Square
130 N. 18th Street, Suite 1600
Philadelphia, PA 19103
(215) 735-0773
tfinken@anapolweiss.com

ATTORNEY FOR PLAINTIFFS

KELLER LENKNER LLC
BY: Ashley Keller (*pro hac vice forthcoming*)
150 N. Riverside Plaza, Suite 4100
Chicago, Illinois 60606
Telephone: (312) 741-5220
Fax: (312) 971-3502
Email: ack@kellerlenkner.com

ATTORNEY FOR PLAINTIFFS

WALSH LAW PLLC
BY: Alex Walsh (*pro hac vice forthcoming*)
1050 Connecticut Ave, NW, Suite 500
Washington, D.C. 20036
Telephone: (202) 780-4127
Fax: (202) 780-3678
Email: awalsh@alexwalshlaw.com

ATTORNEY FOR PLAINTIFFS

TERRAINE ABDULLAH, on her own Behalf and as Parent and Natural Guardian of H.S., a Minor 335 Passmore Street Philadelphia, PA 19111 Plaintiffs	:	COURT OF COMMON PLEAS PHILADELPHIA COUNTY
v.	:	CIVIL ACTION
MEAD JOHNSON & COMPANY, LLC Illinois Corporation Service Co. 801 Adlai Stevenson Drive Springfield, IL 62703	:	NO.
MEAD JOHNSON NUTRITION COMPANY Illinois Corporation Service Co. 801 Adlai Stevenson Drive Springfield, IL 62703	:	
ABBOTT LABORATORIES	:	

CT Corporation System
208 So. Lasalle Street, Suite 814
Chicago, IL 60604

THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM d/b/a PENNSYLVANIA HOSPITAL
3400 Civic Center Blvd.
Philadelphia, PA 19104

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA d/b/a PENN MEDICINE
133 South 36th Street
Philadelphia, PA 19104

Defendants : **JURY TRIAL DEMANDED**

COMPLAINT IN CIVIL ACTION

NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA BAR ASSOCIATION
LAWYER REFERRAL AND INFORMATION SERVICE
ONE READING CENTER
PHILADELPHIA, PA 19107
TELEPHONE: (215) 238-1701

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas las páginas siguientes, usted tiene viente (20) dias de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puese perder dinero o sus propiedades u ostros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO IMMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICO, VAYA EN PERSONA O LLAME POR TELEPHONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ASOCIACION DE LICENCIADOS DE FILADELFIA
Servicio De Referencia E Información Legal
One Reading Center
Filadelfia, Pennsylvania 19107
Telephono: (215) 238-1701

ANAPOL WEISS
BY: TRACY FINKEN, ESQUIRE
IDENTIFICATION NUMBER: 82258
ONE LOGAN SQUARE
130 N. 18TH STREET, SUITE 1600
PHILADELPHIA, PA 19103
(215) 735-0773
TFINKEN@ANAPOLWEISS.COM

ATTORNEY FOR PLAINTIFFS

KELLER LENKNER LLC
BY: ASHLEY KELLER (*PRO HAC VICE FORTHCOMING*)
150 N. RIVERSIDE PLAZA, SUITE 4100
CHICAGO, ILLINOIS 60606
TELEPHONE: (312) 741-5220
FAX: (312) 971-3502
EMAIL: ACK@KELLERLENKNER.COM

ATTORNEY FOR PLAINTIFFS

WALSH LAW PLLC
BY: ALEX WALSH (*PRO HAC VICE FORTHCOMING*)
1050 CONNECTICUT AVE, NW, SUITE 500
WASHINGTON, D.C. 20036
TELEPHONE: (202) 780-4127
FAX: (202) 780-3678
EMAIL: AWALSH@ALEXWALSHLAW.COM

ATTORNEY FOR PLAINTIFFS

TERRAINE ABDULLAH, ON HER OWN BEHALF AND AS PARENT AND NATURAL GUARDIAN OF H.S., A MINOR 335 PASSMORE STREET PHILADELPHIA, PA 19111 PLAINTIFFS	COURT OF COMMON PLEAS PHILADELPHIA COUNTY
V.	CIVIL ACTION
MEAD JOHNSON & COMPANY, LLC ILLINOIS CORPORATION SERVICE CO. 801 ADLAI STEVENSON DRIVE SPRINGFIELD, IL 62703	
	NO.
MEAD JOHNSON NUTRITION COMPANY ILLINOIS CORPORATION SERVICE CO. 801 ADLAI STEVENSON DRIVE SPRINGFIELD, IL 62703	
ABBOTT LABORATORIES CT CORPORATION SYSTEM 208 SO. LASALLE STREET, SUITE 814 CHICAGO, IL 60604	
THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM D/B/A PENNSYLVANIA	

HOSPITAL **3400 CIVIC CENTER BLVD.** **PHILADELPHIA, PA 19104**	:	
THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA D/B/A PENN MEDICINE **133 SOUTH 36TH STREET** **PHILADELPHIA, PA 19104**	:	
DEFENDANTS	:	**JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff brings this Complaint and Demand for Jury Trial (the "Complaint") against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories (collectively "the Defendant Manufacturers"), and The Trustees of the University of Pennsylvania d/b/a Penn Medicine and Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively "Penn Medicine" or "Pennsylvania Hospital"), together "Defendants." Plaintiff alleges the following upon personal knowledge as to Plaintiff's own acts and experiences and upon information and belief, including investigation conducted by Plaintiff's attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the "Injured Infant") who was given the Defendant Manufacturers' cow's milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers' products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis ("NEC"), a life-altering and potentially deadly disease that largely affects premature babies who are given cow's milk-based feeding products. As a result,

the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent ("the Plaintiff Parent").

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant's consumption of the Defendant Manufacturers' unreasonably dangerous cow's milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Terraine Abdullah is a natural adult person and a resident of Pennsylvania. Ms. Abdullah is the parent and natural guardian of H.S., a minor. Ms. Abdullah's address is 335 Passmore Street, Philadelphia, Pennsylvania 19111.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, "Mead") are manufacturers of cow's milk-based infant feeding products and market many of these products under the "Enfamil" brand name.

5. Defendant Abbott Laboratories ("Abbott") is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow's milk-based infant feeding products and markets many of its products under the "Similac" brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of $50,000.

IV. FACTUAL ALLEGATIONS

H.S.'s NEC Diagnosis

11. H.S. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 12, 2006.

12. Upon information and belief H.S. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after her birth.

13. Upon information and belief shortly after H.S. first ingested the Defendant Manufacturers' products, she developed NEC.

14. H.S. was forced to undergo surgery and has continued to suffer long term health effects.

Cow's Milk-Based Feeding Products Are Known to Cause NEC

15. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

16. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

17. For example, in one randomized, multicenter study of 926 preterm infants, NEC was six to ten times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was 20 times more common in those only fed cow's milk formula than in those fed breast milk.

18. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

19. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

20. A Surgeon General report, The Surgeon General's Call to Action to Support Breastfeeding, warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are 138% more likely to develop NEC.

21. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults," has advised that all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based on the "potent benefits of human milk," including "lower rates of . . . NEC."

22. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time.

23. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives To Cow's Milk-Based Products Exist

24. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

25. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

26. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

27. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

28. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

29. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge.

The Defendant Manufacturers' False And Misleading Marketing Regarding Cow's Milk-Based Infant Products

30. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

31. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

32. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

33. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message, with one study estimating that formula manufacturers collectively spent $4.48 billion on marketing and promotion in 2014 alone.

34. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

35. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

36. For example, Abbott's website, on a paged titled "Infant Formula Marketing," states: "We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

37. Abbott markets and sells multiple products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

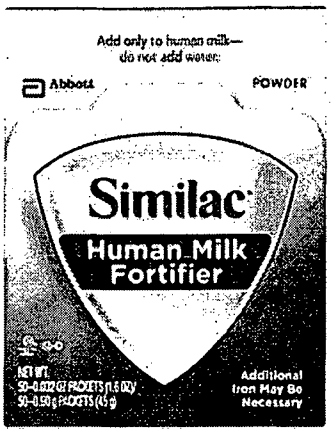
38. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: "Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants" and noted that Enfamil formulas include "expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development."

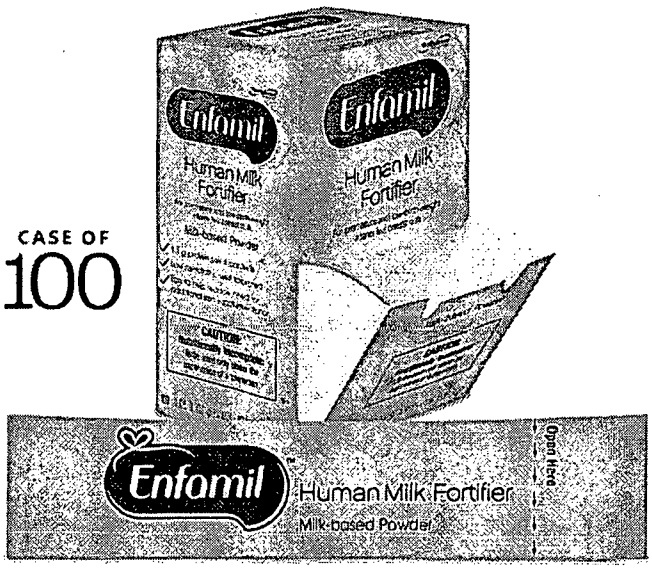
39. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in the advertisement, including in such statements as "for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk" and "only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk." The webpage for the product has made similar manipulative claims, stating "Enfamil is backed by decades of breast milk research and multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]"

40. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants' discharge from the NICU or hospital.

41. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

42. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:





43. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

The Defendant Manufacturers' Inadequate Warnings

44. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

45. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

46. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

47. Mead cites no medical literature or research to guide the use of its products.

48. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

49. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

50. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

51. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

52. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

53. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

54. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

55. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

56. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of those

dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

57. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience "changing hospital systems and influencing policy," and its findings were unequivocal:

> This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that "[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC)."

58. Penn Medicine also purports to adhere to the tenets of the "Baby Friendly Hospital Initiative," which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The "Baby Friendly Hospital Initiative" specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its "Baby Friendly" designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

59. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers' cow's milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

> Donor milk is not inexpensive. It costs about $4.25 per ounce, but the return on investment is huge. "Preemies given mother's milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis," Carpenter said, adding that the infection can cost up to $250,000 to treat. The average cost to provide a preemie with donor milk: $125.

60. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers' products.

61. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers' products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

62. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategy, which aims to "sell and service" healthcare professionals and medical staff as a means of converting them into "extra salespersons."

Safer Alternative Designs

63. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

64. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

65. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION

COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

66. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

67. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

68. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

69. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

70. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

71. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

72. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

73. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

74. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

75. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)

76. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

77. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of

their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

78. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

79. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or

b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failed to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or

e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or

h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

80. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

81. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused and/or increased risk of their developing NEC.

82. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the

Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

83. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT III: NEGLIGENCE
(Against Abbott and Mead)

84. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

85. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

86. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

87. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

88. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or

b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or

e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or

h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

89. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

90. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

91. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

92. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)

93. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

94. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

95. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

96. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

97. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That cow's milk-based products were safe for premature infants; and/or

e. That cow's milk-based products were necessary for optimum growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

98. Abbott and Mead knew or reasonably should have known those misrepresentations to be false.

99. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.

100. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional

misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

101. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

102. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT V: NEGLIGENT MISREPRESENTATION
(Against Abbott and Mead)

103. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

104. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

105. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

106. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

107. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That cow's milk-based products were safe for premature infants; and/or

e. That cow's milk-based products were necessary for optimum growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

108. Abbott and Mead were negligent or careless in not determining those representations to be false.

109. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

110. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent

misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

111. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

112. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)

113. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

114. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

115. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

116. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

117. Penn Medicine and Pennsylvania Hospital negligently and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

118. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives

an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

119. Penn Medicine and Pennsylvania also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

120. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

121. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or

b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or

f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or

g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

122. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

123. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

124. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

125. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

126. As a further direct and proximate result of Penn Medicine and Pennsylvania failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, reckless, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)

127. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

128. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

129. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

130. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

131. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute,

and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

132. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

133. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

134. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

135. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or

b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or

c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or

g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to

Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or

h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

136. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

137. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

138. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

139. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent and reckless conduct the Plaintiff Parent suffered significant emotional distress, loss of

income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

140. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

141. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

142. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or

b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or

c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or

e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice

about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or

h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or

i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

143. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

144. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

145. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

146. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

147. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, , the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

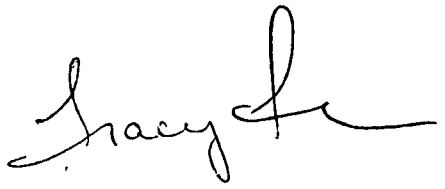
DEMAND FOR JURY TRIAL

148. Plaintiff hereby demands a jury trial for all claims triable.

Dated: March 24, 2022

Respectfully submitted,

ANAPOL WEISS



Tracy Finken
130 N. 18th Street, Suite 1600
Philadelphia, PA 19103
Phone: (215) 735-1130
Email: tfinken@anapolweiss.com

KELLER LENKNER LLC
Ashley Keller (*pro hac vice forthcoming*)
150 N. Riverside Plaza, Suite 4100
Chicago, Illinois 60606

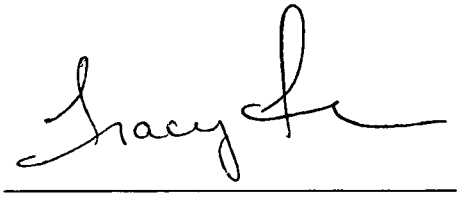
Telephone: (312) 741-5220
Fax: (312) 971-3502
Email: ack@kellerlenkner.com

WALSH LAW PLLC
Alex Walsh (*pro hac vice forthcoming*)
1050 Connecticut Ave, NW, Suite 500
Washington, D.C. 20036
Telephone: (202) 780-4127
Fax: (202) 780-3678
Email: awalsh@alexwalshlaw.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

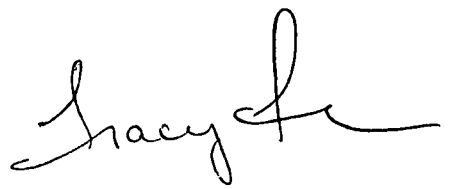
I hereby certify that on March 24, 2022, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.



Tracy Finken

VERIFICATION

I, the undersigned, Tracy Finken, verify that the statements made in this document are true and correct to the best of my knowledge, information, and belief. I understand that false statements herein are made subject to the penalties of 18 Pa. C.S. §4904, relating to unsworn falsification to authorities.



Date: March 24, 2022

Tracy Finken

EXHIBIT A-2

B&R Services for Professionals Inc.
235 SOUTH 13TH STREET
PHILADELPHIA, PA 19107
PHONE: (215) 546-7400
FAX: (215) 985-0169

National Association of Professional Process Servers

Terraine Abdullah, et al.

-VS-

Mead Johnson & Company, LLC, et al.

COURT Court of Common Pleas of Pennsylvania
Philadelphia County - Civil

Filed and Attested by the Office of Judicial Records
02 APR 2022 10:13 am
S. RICE

CASE NUMBER 220302583

AFFIDAVIT

State of Pennsylvania
County of Philadelphia

B&R Control # CS186319.01
Reference Number

James Davis, being duly sworn according to law, deposes and says that he/she is the process server/sheriff herein named, and that the facts set forth below are true and correct to the best of their knowledge, information and belief.

On 3/29/2022 we received the **Civil Action Complaint** and that service was effected upon **The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital** at **2929 WALNUT STREET, PHILADELPHIA, PA 19104** on **3/30/2022** at **11:46 AM**, in the manner described below:

By service upon: NANCY F. VANTRIESTE, CLAIMS ADMINISTRATOR as an agent or person authorized to accept service at usual place of business.

Description:
Gender: **FEMALE** Race/Skin: **WHITE** Age: Weight: Height: **5ft9in - 6ft0in** Hair: **BROWN** Glasses: **Yes** Other:

Service Notes:

Commonwealth of Pennsylvania - Notary Seal
BRENDA M. RAVENELL, Notary Public
Philadelphia County
My Commission Expires December 16, 2023
Commission Number 1266310

Sworn to and subscribed before me this
5th **day of** April 2022

Process Server/Sheriff

Notary Public

ATTEMPTS:

Client Phone (215) 735-1130 : **Filed Date:** 03/24/2022 **BR Serve By:** 04/08/2022

Tracy A. Finken, Esquire
Anapol Weiss
One Logan Square, Suite 1600
130 North 18th Street
Philadelphia, PA 19103

ORIGINAL

EXHIBIT A-3

B&R Services for Professionals Inc.
235 SOUTH 13TH STREET
PHILADELPHIA, PA 19107
PHONE: (215) 546-7400
FAX: (215) 985-0169

NAPPS National Association of Professional Process Servers

Terraine Abdullah, et al.

-VS-

Mead Johnson & Company, LLC, et al.

COURT Court of Common Pleas of Pennsylvania
Philadelphia County - Civil

Filed and Attested by the Office of Judicial Records
APR 2022 09:48 am
S. RICE

CASE NUMBER 220302583

AFFIDAVIT

State of Pennsylvania
County of Philadelphia

B&R Control # CS186319.02
Reference Number

James Davis, being duly sworn according to law, deposes and says that he/she is the process server/sheriff herein named, and that the facts set forth below are true and correct to the best of their knowledge, information and belief.

On 3/29/2022 we received the **Civil Action Complaint** and that service was effected upon **The Trustees of the University of Pennsylvania d/b/a Penn Medicine** at **2929 WALNUT STREET PHILADELPHIA PA. 19104** on **03/30/2022** at **11:48 AM**, in the manner described below:

By service upon: NANCY F. VANTREISTE, CLAIMS ADMINISTRATOR as an agent or person authorized to accept service at usual place of business.

Service Notes:

Commonwealth of Pennsylvania - Notary Seal
BRENDA M. RAVENELL, Notary Public
Philadelphia County
My Commission Expires December 16, 2023
Commission Number 1266310

Sworn to and subscribed before me this
5th **day of** April 2022

Process Server/Sheriff

Notary Public

ATTEMPTS:

Client Phone (215) 735-1130 : **Filed Date:** 03/24/2022 **BR Serve By:** 04/08/2022

Tracy A. Finken, Esquire
Anapol Weiss
One Logan Square, Suite 1600
130 North 18th Street
Philadelphia, PA 19103

ORIGINAL

EXHIBIT A-4

Terraine Abdullah, on her own behalf and as Parent and Natural Guardian of H.S., a minor Plaintiffs v. MEAD JOHNSON & COMPANY, LLC, et al. Defendants.	COURT OF COMMON PLEAS PHILADELPHIA COUNTY CIVIL DIVISION MARCH TERM, 2022 NO. 2583

ORDER

AND NOW, this day of 2022, upon consideration of the Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that all claims against Defendants the Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine are hereby **DISMISSED** with prejudice.

BY THE COURT:

_____

J.

Terraine Abdullah, on her own behalf and as Parent and Natural Guardian of H.S., a minor Plaintiffs v. MEAD JOHNSON & COMPANY, LLC, et al. Defendants.	COURT OF COMMON PLEAS PHILADELPHIA COUNTY CIVIL DIVISION MARCH TERM, 2022 NO. 2583

ALTERNATIVE ORDER

AND NOW, this day of 2022, upon consideration of the Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Complaint, and any Response thereto, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. It is further **ORDERED** that:

1. Count VI of Plaintiffs' Complaint is **DISMISSED** with prejudice;

2. Count VII of Plaintiffs' Complaint is **DISMISSED** with prejudice;

3. Plaintiffs' claims for punitive damages as to Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine are **DISMISSED** with prejudice, along with all allegations of oppressive, reckless, malicious and/or fraudulent conduct;

4. Plaintiff Terraine Abdullah's claims in her own right are **DISMISSED** with prejudice; and

5. Plaintiffs' Complaint is **STRICKEN** for lack of an appropriate verification.

BY THE COURT:

_____

J.

BURNS WHITE LLC
By: James A. Young, Esq.
Richard S. Margulies, Esq.
Attorney ID Nos. 00213/62306
1880 John F. Kennedy Boulevard, 10th Floor
Philadelphia, PA 19103
215-587-1625/1628
jayoung@burnswhite.com
rsmargulies@burnswhite.com

Attorneys For Defendants,
The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine

Terraine Abdullah, on her own behalf and as Parent and Natural Guardian of H.S., a minor Plaintiffs v. MEAD JOHNSON & COMPANY, LLC, et al. Defendants.	COURT OF COMMON PLEAS PHILADELPHIA COUNTY CIVIL DIVISION MARCH TERM, 2022 NO. 2583

PRELIMINARY OBJECTIONS OF DEFENDANTS THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM AND THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA TO PLAINTIFFS' COMPLAINT

Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System ("Pennsylvania Hospital") and the Trustees of the University of Pennsylvania (hereinafter "Moving Defendants") hereby preliminarily object to Plaintiffs' Complaint, and, in support thereof, aver as follows:

I. INTRODUCTION

1. Plaintiffs instituted this action via the filing of a Complaint on March 24, 2022 against Moving Defendants as well as Co-Defendants Mead Johnson & Company, LLC, Mead Johnson Nutritional Company (collectively referred to as "Mead Johnson") and Abbott Laboratories ("Abbott"). See Plaintiff's Complaint, attached as Exhibit "A."

2. Plaintiffs have filed a slew of essentially identical lawsuits against Pennsylvania Hospital and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow's milk-based infant formula by premature infants following their birth.[1]

3. Plaintiffs allege that "upon information and belief" the Plaintiff-minors, including H.S., were diagnosed with necrotizing enterocolitis (NEC), a gastrointestinal disorder that premature infants are at increased risk to develop. *See* Plaintiffs' Complaint, attached as Exhibit "A," ¶ 13. Plaintiffs allege that premature infants fed with their mother's breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow's milk-based infant formula.[2]

4. In addition to asserting product liability claims against the infant formula manufacturers Mead Johnson and Abbott, Plaintiffs have alleged that Moving Defendants are liable based on theories of failure to warn and corporate liability. [3]

5. The factual background regarding the Plaintiff-minor's birth, diagnosis and injuries are limited to four paragraphs in the Complaint.

[1] Lawsuits involving identical claims have been filed against the Hospital of the University of Pennsylvania, Temple University Hospital, Albert Einstein Medical Center and Thomas Jefferson University Hospital.

[2] Although Plaintiffs aver in the Complaint that NEC is caused by cow's milk-based infant formula, as discussed infra and in the accompanying Memorandum of Law, the allegations in the Complaint refer to research and studies that indicate only that NEC is *more common* in premature and low birth weight infants fed with cow's milk-based products as compared with similar infants fed with breast milk. *See* Exhibit "A," ¶¶ 17-23. Plaintiffs do not cite any study or statement in the Complaint that indicates NEC is caused by cow's milk-based infant formula.

[3] As is discussed in detail in the accompanying Memorandum of Law, infant formulas are regulated by the United States Food and Drug Administration and require to include specified vitamins and nutrients, including infant formulas intended for low birth weight infants. The FDA permits does not restrict the use of cow's milk-based infant formula for premature or low birth weight infants. Plaintiff's contention that cow's milk-based infant formula should never be given to premature infants is not supported by the FDA.

6. Plaintiffs aver that H.S. was born prematurely on September 12, 2006 and that "upon information and belief was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after her birth." *Id.*, ¶¶ 11-12.

7. Plaintiffs further allege that "upon information and belief" H.S. developed NEC shortly after first ingesting the Defendant manufacturers' products. *Id.*, ¶ 13.

8. Plaintiffs generally allege that H.S. "suffered injuries and has continued to suffer long-term health effects," with no specific description of those alleged injuries or long-term health effects. *Id.*, ¶ 14.

9. Moving Defendants Preliminarily Object to Plaintiffs' Complaint for the reasons stated below and as more fully set forth in the accompanying Memorandum of Law, which is incorporated herein by reference.

II. ARGUMENT

A. DEMURRER TO COUNT VI: FAILURE TO WARN

10. Plaintiffs allege in Count VI of the Complaint that Moving Defendants, "as purchaser, supplier, and/or distributor of the products at issue in the litigation" owed Plaintiffs and the public a duty to provide products that were free of unreasonable risk of harm.

11. Plaintiffs' theory against Moving Defendants is that they were aware cow's milk-based products made by the Defendant Manufacturers cause NEC in premature and low birth weight infants and negligently failed to warn the parents of those infants of this danger.

12. In support of this theory, Plaintiffs cite to five studies comparing cow's milk-based products to breast milk, a Surgeon General report on the subject, and a statement by the American Academy of Pediatrics. *See* Exhibit "A," ¶¶ 17-23.

13. Taking these facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to demonstrate the product in question is indeed unreasonably dangerous.

14. Further, to the extent the product at issue was provided in the context of medical care, rather than commerce, there can be no claim against Moving Defendants for a product-liability based theory of failure to warn.

15. "Pennsylvania has adopted the Restatement (Second) of Torts in cases involving a claim of negligent failure to warn." *Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.*, 596 A.2d 845, 850 (Pa. Super. 1991). Section 388 governs this cause of action, and provides:

> One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
>
> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
>
> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
>
> (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts § 388.

16. "The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous." *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998).

17. "A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use." *Id.* At 308.

18. Based on the foregoing, Plaintiffs must aver sufficient facts demonstrating the Defendant Manufacturers' products are unreasonably dangerous for their intended use, triggering Moving Defendants' duty to warn.

19. Although Plaintiffs cite in their Complaint to research studies relating to the purported risks of cow's milk-based products in premature infants, the studies demonstrate only, assuming the facts as true as stated by Plaintiffs, that premature infants are at high risk of NEC, and that feeding such infants with breast milk may be better at reducing the risk of NEC than cow's milk-based alternatives. *See* Exhibit "A," ¶¶ 17-23.

20. At the outset, Plaintiffs appropriately acknowledge that "[p]reterm and low-birth-weight infants are *especially susceptible to NEC*." See Exhibit "A" at ¶ 16 (emphasis added). Following this, Plaintiffs make the core claim of their Complaint – that cow's milk-based feeding products cause NEC in preterm and low birth weight infants – and that "[e]xtensive scientific research, including numerous randomized controlled trials" confirm this claim. *Id.* However, reviewing the portions of the research and trials cited by Plaintiffs in their Complaint belie their core claim.

21. The first study cited by Plaintiffs states, according to the Complaint, that "NEC was six to ten times *more common* in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times *more common* in babies who received a combination of formula and breast milk." *Id.* at ¶ 17 (emphasis added). To say that NEC is more common in infants fed cow's milk-based products than those fed breast milk is to say that NEC **still occurs in infants fed exclusively breast milk**, but only at a lower rate. Thus, Plaintiffs' first study does not state cow's milk-based feeding products causes NEC.

22. As averred in the Complaint, the second study cited by Plaintiffs states that "preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC compared to preterm babies fed a diet that included some cow's milk-based products." *Id.* at ¶ 18. To state that preterm infants fed only breast milk are **less likely** to develop a form of NEC is to admit that NEC still develops in preterm infants **regardless of the diet.** Thus, Plaintiffs' second study likewise does not state that cow's milk-based feeding products cause NEC.

23. The third study cited by Plaintiffs concluded, per the Complaint, "fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death compared to fortification with a breast milk-based fortifier." *Id.* at ¶ 19. What the study does not state, as alleged in the Complaint, is that cow's milk-based fortifiers cause NEC.

24. The Surgeon General report cited by Plaintiffs is alleged in the Complaint to reiterate the principle made in the prior three studies and states that "formula feeding is associated with *higher rates*" of NEC in preterm infants and that "premature infants who are not breastfed are 138% more likely to develop NEC." *Id.* at ¶ 20 (emphasis added). If cow's milk-based formula caused NEC as Plaintiffs aver, one might expect the Surgeon General report to so state. Instead, the Surgeon General report, as described in Plaintiffs' Complaint at ¶ 20, makes the same acknowledgment as Plaintiffs – that preterm infants are highly susceptible to NEC regardless of their diet, and that NEC occurs in different rates in preterm infants fed cow's milk-based products and breast milk. The report does not state that the former causes NEC.

25. According to the Complaint, the American Academy of Pediatrics makes a nearly identical statement to the Surgeon General report. *Id.* at ¶ 21. The Academy makes a recommendation that "all premature infants should be fed either their mother's milk or, if their

mother's milk is unavailable, pasteurized donor milk," which recommendation is alleged to be related in part to "lower rates… of NEC." *Id.* This statement acknowledges that NEC still occurs in preterm infants fed only breast milk, but simply at a lower rate. According to the Complaint, the Academy does not claim that cow's milk-based feeding products cause NEC.

26. The fourth and fifth studies cited by Plaintiffs in their Complaint provide similar information. As alleged in the Complaint, a study "found that premature and low-birth-weight infants fed an exclusive breast-mild-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time." In another study, as alleged in the Complaint, "babies given exclusively breast milk products suffered NEC 5% of the time," whereas "babies given cow's milk products suffered NEC 17% of the time." *Id.* at ¶ 22-23. Once again, these studies, based on the allegations in Plaintiffs' Complaint, do not state that cow's milk-based formula causes NEC.

27. Thus, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to state facts to establish that cow's milk-based infant formula is unreasonably dangerous for its intended purpose.

28. Further, assuming *arguendo* that the Defendant Manufacturers' cow's milk-based feeding products can be seen as unreasonably dangerous for their intended use as opposed to simply being a less effective alternative to breast milk products, Moving Defendants still had no duty to warn of the nature of cow's milk-based products under § 388 because medical providers are not "supplying" a product to a patient within the stream of commerce.

29. Plaintiffs' failure to warn claim is similarly precluded to the extent that Plaintiffs are alleging that Defendants, in providing medical care to Plaintiff-minor, failed to obtain Plaintiff-

parent's consent to the use of cow's milk-based products and failed to warn of the purported risks and alternatives of such products.

30. The sole basis upon which Plaintiffs can proceed against Moving Defendants for "failure to warn" in the context of providing medical care is to assert such a claim under a theory of failure to obtain informed consent.

31. Claims for informed consent in medical malpractice actions are governed by the Medical Care Availability and Reduction of Error Act, which provides as follows:

> (a) **Duty of Physicians**.--Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:
>
> (1) Performing surgery, including the related administration of anesthesia.
>
> (2) Administering radiation or chemotherapy.
>
> (3) Administering a blood transfusion.
>
> (4) Inserting a surgical device or appliance.
>
> (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.
>
> (b) Description of procedure.--Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted standards of medical practice would provide.

40 P.S. §1303.504 (emphasis added).

32. Since the use of infant formula in feeding premature infants is not a "procedure," there is no basis for Plaintiffs to contend that Plaintiff-parent's consent was required for the use of infant formula to feed her infant, including warning her of the risks or alternatives of same.

33. Further, the informed consent statute only applies to physicians, not hospitals, in the context of medical procedures. *See Morgan v. MacPhail*, 550 Pa. 202, 205 (1997).

34. Thus, a hospital cannot be held liable for a physician's failure to obtain proper informed consent. *Valles v. Albert Einstein Medical Center*, 805 A.2d 1232 (2002).

B. DEMURRER TO COUNT VII: CORPORATE LIABILITY OF HEALTH CARE PROVIDER

35. In *Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991), the Pennsylvania Supreme Court recognized the doctrine of corporate liability, holding that a hospital may be found directly liable for negligence if it fails to meet *any* of the following four duties: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.

36. Plaintiffs' corporate liability claim fails based on the same rationale as the claim for failure to warn, since both claims are based on the alleged failure to provide warnings to patients related to the use of cow's milk-based infant formula.

37. Infant formula is regulated by the FDA, and there is no legal restriction on the use of cow's milk-based products for feeding of premature infants.

38. Indeed, the Infant Formula Act expressly acknowledges that it is permissible to provide cow's-milk based products to low birth weight infants.

39. Further, as discussed above, Plaintiffs cannot demonstrate that cow's milk-based formula is an unreasonably dangerous product.

40. Thus, there is no legal basis to contend that Moving Defendants can be held liable pursuant to a theory of corporate liability for failing to prevent the use of cow's milk-based products in the feeding of premature infants in the hospital.

41. Additionally, Courts considering the application of the duties set forth in *Thompson* have insisted on more than a simple finding of a negligent act by someone for whom the hospital is purportedly responsible. *Edwards v. Brandywine Hospital*, 652 A.2d 1382 (Pa. Super. 1995).

42. In considering whether the plaintiff could sustain corporate negligence claims based on these allegations, the *Edwards* court analyzed the Thompson decision and delineated the standards required to sustain such a claim:

> The *Thompson* theory of corporate liability **will not be triggered every time something goes wrong in a hospital which harms a patient** . . . To establish corporate negligence, a plaintiff must show more than an act of negligence by an individual for whom the hospital is responsible. Rather, Thompson requires a plaintiff to show that the hospital itself is breaching a duty and is somehow substandard…*Thompson* contemplates a kind of '**systemic negligence**'…

Id. at 1386-87 (citations omitted and emphasis added).

43. Thus, a hospital may not be held liable via corporate negligence simply based on the alleged negligence of an individual health care provider.

44. Accordingly, even if Plaintiffs could establish that the use of cow's milk-based infant formula was a breach of the standard of care by unidentified health care providers based on the specific circumstances of the Plaintiff-minor's case herein, which has not been pleaded by Plaintiffs considering the paucity of the allegations in the Complaint, such evidence cannot support a finding of corporate liability.

45. Additionally, even assuming Plaintiffs had a viable corporate negligence claim against Pennsylvania Hospital, any such claim is precluded against the Trustees of the University of Pennsylvania since it is not a hospital.

46. The *Thompson* holding has been extended to HMO's and nursing home facilities, where it was determined that such entities performed similar functions as hospitals. *See Shannon v. Health America Pennsylvania, Inc.*, 718 A.2d 828 (Pa. Super. 1998); *Scampone v. Highland Park Care Center, LLC*, 57 A.3d 582 (Pa. 2012).

47. However, courts have routinely refused to extend the *Thompson* holding past such institutions to cover other entities, such as medical clinics and physician practice groups. *See Sutherland v. Monongahela Valley Hospital*, 856 A.2d 55, 62 (Pa. Super. 2004); *Dowhouer v. Judson*, 45 Pa. D. & C.4th 172, 180 (Pa.Com.Pl. 2000); *Brewer v. Geisinger Clinic, Inc.*, 45 Pa. D. & C.4th 215, 223 (Pa.Com.Pl. 2000); *Dibble v. Penn State Geisinger Clinic, Inc.*, 42 Pa. D. & C.4th 225 (Pa.Com.Pl. 1999); *Davis v. Gish*, 5 Pa. D. & C.5th 154, 159 (Pa.Com.Pl. 2007).

48. There is no legal basis for holding that the purported corporate parent of a hospital, such as the Trustees of the University of Pennsylvania, can be held liable under a theory of corporate negligence.

49. Indeed, the *Scampone* Court cautioned that the trial court should ensure that "multiple entities are not exposed to liability for breach of the same non-delegable duties." 57 A.2d at 606-07.

C. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

50. Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading.

51. A plaintiff's Complaint is required to provide a defendant with notice of what the plaintiff's claims are and the grounds upon which they rest, and the complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (*citations omitted*).

52. Pennsylvania Rule of Civil Procedure 1019(a) provides that "the material facts on which a cause of action or defense is based shall be stated in a concise and summary form." Pa.R.C.P. 1019(a). As the Superior Court has noted,

> Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.**

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted)(emphasis added).

53. Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See, also, Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) ("A catchall averment of "other injuries" is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.")

54. Plaintiffs' Complaint is woefully deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case.

55. Plaintiffs' description of the material facts relating to the minor's care and treatment, diagnosis and injuries is limited to four paragraphs, which are utterly insufficient to enable defendants to prepare their defenses. *See* Exhibit "A," ¶¶ 11-14.

56. Plaintiffs aver that the minor was born prematurely but do not identify the gestational age at which the child was born or her birth weight. Plaintiffs' allegation that "upon information and belief," the minor was fed Similac and/or Enfamil shortly after her birth (*Id.* at ¶ 12) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide defendants with appropriate notice of the facts as to whether the minor actually ingested cow's milk-based products.

57. Further, plaintiffs have failed to identify which of the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor. *Id.* at ¶¶ 37-38.

58. Plaintiffs' Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC and what treatment was provided for that condition.

59. The Complaint further fails to state the nature of the injuries and "long-term health effects" that are alleged to have resulted from the diagnosis of NEC.

60. Plaintiffs' damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change.

61. These omissions are fatal defects in Plaintiff's Complaint. Therefore, Plaintiffs' Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

62. In the *Ad Damnum* clauses of Counts VI and VII of the Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of punitive damages. *See* Exhibit "A," pp. 38, 46.

63. However, the Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants.

64. Rather, Plaintiffs merely allege that "upon information and belief" H.S. may have been given a cow's milk-based infant formula following birth, absent any context to indicate that such an action was inappropriate based on the specific issues involved in H.S.'s medical care and condition following birth.

65. For example, the Complaint gives no indication of whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow's milk-based products.

66. Plaintiff's allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants.

67. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least five hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants

engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based infant formula.

68. Absent specific factual allegations to justify the claim that the use of infant formula in H.S.'s case was extreme and outrageous, there is no basis for an award of punitive damages in this case.

69. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of the claim.

70. Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that "punitive damages are an 'extreme remedy' available in only the most exceptional matters." *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec. LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). "In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious." *Wagner* at *12.

71. Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

72. Specifically, with regard to punitive damages in the context of claims against health care providers, the Medical Care and Reduction of Error (MCARE) Act permits punitive damages only to be awarded as follows:

> (a) Award. -- Punitive damages may be awarded for conduct that is the result of the health care provider's willful or wanton conduct or reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the health care provider's act, the nature and extent of the harm to the patient that the health care provider caused or intended to cause and the wealth of the health care provider.
>
> (b) Gross Negligence. -- A showing of gross negligence is insufficient to support an award of punitive damages.

40 P.S. §1303.505.

73. The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, "the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious." *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772.

74. Thus, "a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk." *Id.*

75. Since professional negligence actions involve allegations that health care professionals deviated from the governing standard of care, punitive damages are generally not recoverable in malpractice actions unless the medical provider's deviation from the applicable standard of care is so egregious as to evince a conscious or reckless disregard of a patent risk of harm to the patient. *Wagner, supra*.

76. Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See*, *e.g.*, *Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that "**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.") (emphasis added); *Wagner*, *supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted "nothing more than ordinary negligence and are insufficient to support an award of punitive damages."); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that "[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct of defendants that is at issue."); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not "capable of pleading the requisite behavior" for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

77. Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See*, *e.g.*, *Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3rd

Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer's patient where he repeatedly raped her, since nursing home was aware of resident's prior criminal convictions for sex registration as a sexual offender under Megan's Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

78. The facts underlying Plaintiffs' bare assertions of reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages.

79. Additionally, pursuant to § 505(c) of the MCARE Act, punitive damages are specifically restricted in claims involving vicarious liability:

> (c) Vicarious liability. -- Punitive damages shall not be awarded against a healthcare provider who is only vicariously liable for the actions of its agent that caused the injury unless it can be shown by a preponderance of the evidence that

> the party knew of and allowed the conduct of its agent that resulted in an award of punitive damages.

40 P.S. §1303.505(c).

80. Plaintiffs allege in this action that unidentified "staff" fed H.S. Similac and/or Enfamil at Pennsylvania Hospital shortly after her birth and failed to warn Plaintiff-parent of the alleged risks of such products. See Exhibit "A," ¶ 12.

81. Even if such actions were claimed to be egregious or malicious such that punitive damages were permissible, which is denied for the reasons stated above, Plaintiffs must allege facts to establish that Moving Defendants had actual knowledge of the alleged wrongful conduct and nevertheless allowed it. *See Zazzera v. Roche*, 54 D. & C. 4th 225, 238 (Pa. Com. Pl. 2001); *Dean Witter Reynolds, Inc. v. Genteel*, 499 A.2d 637 (Pa. Super. 1985).

82. In this matter, Plaintiffs have failed to plead any facts to suggest that Moving Defendants were aware of any alleged misconduct by any individual alleged to be an agent and allowed such conduct to continue.

83. For all these reasons, Plaintiffs' demand for punitive damages must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO DISMISS PLAINTIFF-PARENT'S CLAIMS

84. Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of H.S.

85. Plaintiffs' Complaint includes allegations in each count asserted as to Moving Defendants in which it is averred that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly altered by the Injured Infant's injuries." *See* Exhibit "A," ¶¶ 126, 139 and 147.

86. However, no specific cause of action is asserted as to any damages sought by behalf of Plaintiff-parent, who is not alleged in the Complaint to have suffered any physical injuries as a result of the alleged negligent conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

87. Further, even if Plaintiff-parent had properly articulated a cause of action in the Complaint to allow her to recover damages in her own right, the Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

> If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

88. Accordingly, it is improper for Plaintiffs to plead in a single count claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the Complaint filed herein. Claims on behalf of each of the Plaintiffs must be set forth in separate counts of the Complaint, specifically identifying the cause of action asserted and relief sought in each count.

89. Additionally, although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. *See Hathi v. Krewstown Park Apts*, 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524.

90. Plaintiffs allege that H.S. was born on September 12, 2006, was fed the Defendant manufacturers' products shortly after her birth, and developed NEC shortly thereafter. *See* Exhibit "A," ¶¶ 11-13.

91. Thus, since the Complaint herein was filed on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations.

F. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR FAILURE TO COMPLY WITH Pa.R.C.P. 1024

92. Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer's personal knowledge or information and belief.

93. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading.

94. In this case, Plaintiffs' counsel signed the verification for the Complaint, in violation of Rule 1024. *See* Exhibit "A."

95. Accordingly, the Complaint should be stricken for lack of an appropriate verification.

WHEREFORE, Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine respectfully request that this Honorable Court sustain the instant Preliminary Objections and enter the attached proposed Order.

BURNS WHITE LLC

BY: 

JAMES A. YOUNG, ESQ.
RICHARD S. MARGULIES, ESQ.
Attorneys for Defendants,
The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine

BURNS WHITE LLC
By: James A. Young, Esq.
Richard S. Margulies, Esq.
Attorney ID Nos. 00213/62306
1880 John F. Kennedy Boulevard, 10th Floor
Philadelphia, PA 19103
215-587-1625/1628
jayoung@burnswhite.com
rsmargulies@burnswhite.com

Attorneys For Defendants,
The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine

Terraine Abdullah, on her own behalf and as Parent and Natural Guardian of H.S., a minor Plaintiffs v. MEAD JOHNSON & COMPANY, LLC, et al. Defendants.	COURT OF COMMON PLEAS PHILADELPHIA COUNTY CIVIL DIVISION MARCH TERM, 2022 NO. 2583

MEMORANDUM OF LAW IN SUPPORT OF PRELIMINARY OBJECTIONS OF DEFENDANTS THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM AND THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA TO PLAINTIFFS' COMPLAINT

I. MATTER BEFORE THE COURT

Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System ("Pennsylvania Hospital") and The Trustees of the University of Pennsylvania to Plaintiffs' Complaint.

While patently obvious that Plaintiffs' Complaint must be dismissed for clear and important violations of the procedural requirements governing pleadings and verification of the accuracy of the factual averments of the Complaint (there are not separate counts identified for the causes of action of each of the Plaintiffs attempts to allege), most of which are averred "upon information and belief," the substance of Plaintiffs' allegations do not support any legally

recognized cause of action against Moving Defendants, under Pennsylvania law. Our procedural rules do not permit a plaintiff to simply identify allegedly tortious conduct by a defendant without pleading the necessary facts to satisfy the elements of the tortious conduct.

Here, Plaintiffs plead that Moving Defendants permitted Co-Defendants' cow's milk-based infant formula to be fed to prematurely born infants, which allegedly caused those infants to develop necrotizing enterocolitis ("NEC"). Plaintiffs then plead themselves out of Court by attempting to support a "failure to warn" claim by referencing various articles that, as pleaded and for purposes of these Preliminary Objections accepted as true, do not support the contention that cow's milk-based infant formulas cause NEC. Thus, distinct from the Complaint's procedural shortcomings, Plaintiffs have failed to plead facts that support the "failure to warn" and corporate liability causes of action that they attempt to assert against Moving Defendants. It is further noteworthy that there is no viable "failure to warn" cause of action that is recognized under Pennsylvania law against Moving Defendants, as explained in this submission by Moving Defendants.

II. STATEMENT OF QUESTIONS PRESENTED

1. Whether this Honorable Court should dismiss Count VI of Plaintiffs' Complaint "Failure to Warn" cause of action with prejudice because Plaintiffs' Complaint does not support the claim that cow's milk-based products are unreasonably dangerous and Moving Defendants cannot be held liable for negligent failure to warn on the basis that they are a supplier of such products?

Suggested answer in the affirmative.

2. Whether this Honorable Court should dismiss Count VI of Plaintiffs' Complaint "Failure to Warn" cause of action with prejudice because it improperly alleges that Moving

Defendants were required to obtain Plaintiff-parent's informed consent to use of cow's milk-based products for feeding of Plaintiff-minor and warn her of the risks and/or alternatives of same?

Suggested answer in the affirmative.

3. Whether this Honorable Court should dismiss Count VII of Plaintiffs' Complaint "Corporate Negligence" cause of action with prejudice because Moving Defendants cannot be held liable on such a theory for a product which is regulated by the FDA and which is not precluded for use in premature or low birth weight infants, and where a hospital cannot be held liable for corporate negligence based on the alleged negligence of an individual health care provider?

Suggested answer in the affirmative.

4. Whether this Honorable Court should dismiss Count VII of Plaintiffs' Complaint "Corporate Negligence" cause of action with prejudice as to the Trustees of the University of Pennsylvania since it is not a hospital and because corporate negligence duties are non-delegable?

Suggested answer in the affirmative.

5. Whether this Honorable Court should strike Plaintiffs' Complaint in its entirety for insufficient specificity of the facts and alleged injuries?

Suggested answer in the affirmative.

6. Whether this Honorable Court should strike Plaintiffs' claims for punitive damages as to Moving Defendants because the Complaint fails to plead facts providing a basis for an award of punitive damages?

Suggested answer in the affirmative.

7. Whether this Honorable Court should strike Plaintiff-parent's claims for failure to state a cause of action, and for failure to plead separate causes of action pursuant to Pa.R.C.P. 1020 and based on the applicable statute of limitations?

Suggested answer in the affirmative.

8. Whether this Honorable Court should strike Plaintiffs' Complaint for failure to provide a client verification as required by Pa.R.C.P. 1024?

Suggested answer in the affirmative.

III. INTRODUCTION AND FACTUAL BACKGROUND

Plaintiffs have filed a slew of essentially identical lawsuits against Pennsylvania Hospital and other hospitals in Philadelphia based on claims relating to alleged ingestion of cow's milk-based products by premature infants in the hospital following their birth.[1] Plaintiffs allege that the Plaintiff-minors, including H.S., were diagnosed with necrotizing enterocolitis (NEC), a gastrointestinal disorder that premature infants are at increased risk to develop. *See* Plaintiffs' Complaint, attached as Exhibit "A" at ¶ 13. Plaintiffs aver that premature infants fed with their mother's breast milk or donor breast milk are at decreased risk of developing NEC as compared with infants given cow's milk-based products (infant formula). Many of the allegations of the Complaint are pleaded "upon information and belief," including the allegations that Plaintiff-minors received infant formula and that they developed NEC shortly after being fed with infant formula.

In addition to asserting product liability claims against the infant formula manufacturers Mead Johnson & Company, LLC, Mead Johnson Nutritional Company (collectively referred to as "Mead Johnson") and Abbott Laboratories ("Abbott")[2], Plaintiffs have alleged that Moving Defendants are liable based on theories of failure to warn and corporate liability. *See* Plaintiff's

[1] Lawsuits involving identical claims have been filed against the Hospital of the University of Pennsylvania, Temple University Hospital, Albert Einstein Medical Center and Thomas Jefferson University Hospital.

[2] Mead Johnson and Abbott have been the subject of similar lawsuits in other states, including Connecticut, Illinois and California.

Complaint, attached as Exhibit "A" at Counts VI and VII. As is discussed in detail below, Plaintiffs' claims against Moving Defendants are legally and factually deficient.

Although Plaintiffs aver that NEC is caused by cow's milk-based products, Plaintiffs refer in their Complaint to research studies and reports that, as alleged by Plaintiffs, indicate only that NEC is more common in premature and low birth weight infants fed with cow's milk-based products as compared with similar infants fed with breast milk. *See* Exhibit "A," ¶¶ 17-23. As discussed in detail *supra*, assuming the truth of the factual allegations stated in Plaintiffs' Complaint, the research studies cited by Plaintiffs do not support the conclusion that NEC is caused by cow's milk-based products. As such, there is no basis to contend that cow's milk-based products are dangerous for premature infants, such that Moving Defendants had a duty to warn Plaintiff-parents of any risks or alternatives related to infant formula.

Plaintiffs' Complaint provides scant information regarding the factual background of this case. Plaintiffs aver that H.S. was born prematurely on September 12, 2006 and that "upon information and belief was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after her birth." *Id.*, ¶¶ 11-12. Plaintiffs further allege that "upon information and belief" H.S. developed NEC shortly after first ingesting the Defendant manufacturers' products. *Id.*, ¶ 13. No details are provided regarding the extent of her prematurity, her birth weight, or her condition following birth other than that she developed NEC on an unidentified date. Further, no facts are provided by Plaintiffs as to any medical care H.S. received other than surgery for what period of time H.S. allegedly ingested cow's milk-based products, and

which product(s) she allegedly ingested.[3] Finally, the Complaint is silent as to the nature and extent of H.S.'s alleged injuries other than a vague reference to "long term health effects." *Id.* ¶ 14.

Further, the Complaint does not provide any details whatsoever regarding communications between Plaintiff-parent and medical providers at Pennsylvania Hospital regarding the allegations that H.S. may have been fed with Mead Johnson and/or Abbott cow's milk-based products in the hospital. Plaintiffs conceded in the Complaint that mothers are encouraged by their healthcare professionals to breastfeed. *Id.* ¶ 41. However, Plaintiffs do not provide any information regarding discussions between Plaintiff-parent and any health care providers at Pennsylvania Hospital related to breastfeeding and/or using cow's milk-based products in this case, including whether or not she was encouraged to breastfeed and/or was unable or declined to do so. As noted, Plaintiffs plead that Plaintiff Minor ingested formula "on information and belief" only, and similarly plead "on information and belief" that Plaintiff Minor developed NEC as a result.

Plaintiffs further fail to disclose in their Complaint that infant formula is regulated by the United States Food and Drug Administration (FDA) and that there is no restriction on the use of cow's milk-based products for premature infants. The federal Infant Formula Act of 1980 ("IFA") was enacted "to assure the safety and nutrition of infant formulas." Pub. L. No. 96-359, 94 Stat. 1190. The IFA and its implementing regulations outline the requirements that infant formula must meet, including how infant formula is made, its contents and ingredients, and the labels used on its packages. 21 U.S.C. § 350a; 21 C.F.R. §§ 106-07. The IFA provides that infant formulas may only contain "substances that are safe and suitable for use in infant formula." 21 C.F.R. § 106.40(a). Neither the IFA nor the regulations exclude cow milk as an ingredient, and many infant formulas

[3] Plaintiffs aver that Abbott sells at least seven types of products directed to preterm and/or low birth weight infants, six of which use the name Similac, and that Mead Johnson sells eight types of infant formulas using the Enfamil brand name. *Id.*, ¶¶ 37-38.

for sale include cow milk. (Exhibit "A," ¶¶ 37-38); 21 C.F.R. § 106.3 ("infant formula" is a "food for infants by reason of its *simulation* of human milk") (emphasis added). 21 U.S.C. § 350a; 21 C.F.R. §§ 107.50. Before selling any "new infant formula," a manufacturer must (1) register with the FDA, and (2) submit a notice to the FDA at least 90 days before marketing such formula. The notice must also state that the formula contains the required vitamins and nutrients, as demonstrated by testing. 21 U.S.C. § 350a(b). These same FDA review procedures apply when a manufacturer makes a "major change" to an existing formula. 21 U.S.C. § 350a(c)(2)(B); 21 C.F.R. § 106.3.

Further, the FDA recognizes that certain infant formulas are intended for low birth weight babies (such as infants born prematurely) or infants with unusual medical or dietary problems. Indeed, such formulas have special review requirements. 21 U.S.C. § 350a(h); 21 C.F.R. § 107.50(a). For those formulas – known as "exempt" formulas because they may be exempted from certain requirements – the required 90-day notice must include "the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, and a detailed description of the medical conditions for which the infant formula is represented." 21 C.F.R. § 107.50(b)(3). As with other formulas, the regulations do not exclude cow milk as an ingredient for infant formulas intended for use by an infant with a low birth weight.

Thus, since Plaintiffs do not allege that the product did not meet federal requirements, there is no basis for any claim that the product is unreasonably dangerous and/or should not be given under any circumstances to premature or low birth weight infants.

IV. ARGUMENT

A. DEMURRER TO COUNT VI: FAILURE TO WARN

1. Moving Defendants Cannot Be Held Liable to Plaintiffs Based on a Theory of Failure to Warn Because the Infant Formula is Not Unreasonably Dangerous

Pursuant to Pa.R.C.P. 1028(a)(4), a party may file preliminary objections to a complaint, in the nature of a demurrer, for legal insufficiency in a pleading. A court should grant a demurrer where, accepting as true all well pled facts, a legal cause of action cannot be maintained upon those facts. Pa.R.C.P. 1028(a)(4); *See also*, *Willet v. Pennsylvania Med. Catastrophe Loss Fund*, 702 A.2d 850, 853 (Pa. 1997).

Plaintiffs allege in Count VI of the Complaint that Moving Defendants, "as purchaser, supplier, and/or distributor of the products at issue in the litigation" owed Plaintiffs and the public a duty to provide products that were free of unreasonable risk of harm. Plaintiffs' theory against Moving Defendants is that they were aware cow's milk-based products manufactured by Mead Johnson and Abbott cause NEC in premature and low birth weight infants and negligently failed to warn the parents of those infants of this danger. In support of this theory, Plaintiffs cite to five studies comparing cow's milk-based products to breast milk, a Surgeon General report on the subject, and a statement by the American Academy of Pediatrics. Taking these facts as pleaded by Plaintiffs as true, Plaintiffs have failed to state a claim for negligent failure to warn against Moving Defendants as they have failed to demonstrate the products in question are indeed unreasonably dangerous. Further, to the extent the product at issue was provided in the context of medical care, rather than commerce, there can be no claim against Moving Defendants for a product-liability based theory of failure to warn.

"Pennsylvania has adopted the Restatement (Second) of Torts in cases involving a claim of negligent failure to warn." *Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.*, 596 A.2d 845, 850 (Pa. Super. 1991). Section 388 governs this cause of action, and provides:

> One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
>
> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
>
> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
>
> (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts § 388. To survive preliminary objections, Plaintiffs must aver sufficient facts, together with the documents and exhibits attached thereto, to make out a *prima facie* case as to all elements of the cause of action. *Northern Forests II, Inc. v. Keta Realty Co.*, 130 A.3d 19, 35 (Pa. Super. 2015).

"The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous." *Weiner v. American Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. 1998). "A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended use." *Id.* At 308. Whether a product is "unreasonably dangerous" is a question of law. *Id.* Based on the foregoing, Plaintiffs must aver sufficient facts demonstrating the Defendant Manufacturers' products are unreasonably dangerous for their intended use, triggering Moving Defendants' duty to warn. They have not done so as the studies they cite in their Complaint do not

say – based on the very allegations in the Complaint - what Plaintiffs claim they do. Therefore, Moving Defendants had no corresponding duty to warn.

At the outset, Plaintiffs appropriately acknowledge that "[p]reterm and low-birth-weight infants are *especially susceptible to NEC*." See Exhibit "A" at ¶ 16 (emphasis added). Following this, Plaintiffs make the core claim of their Complaint – that cow's milk-based feeding products cause NEC in preterm and low birth weight infants – and that "[e]xtensive scientific research, including numerous randomized controlled trials" confirm this claim. *Id.* Admittedly, if a product directly causes NEC in preterm and low birth weight infants, that product would certainly be dangerous. However, reviewing the portions of the research and trials cited by Plaintiffs in their Complaint belie their core claim.[4]

The first study cited by Plaintiffs states, according to the Complaint, that "NEC was six to ten times *more common* in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times *more common* in babies who received a combination of formula and breast milk." *Id.* at ¶ 17 (emphasis added). To say that NEC is more common in infants fed cow's milk-based products than those fed breast milk is to say that NEC **still occurs in infants fed exclusively breast milk**, but only at a lower rate. Thus, Plaintiffs' first study does not state cow's milk-based feeding products causes NEC.

As averred in the Complaint, the second study cited by Plaintiffs states that "preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC compared to preterm babies fed a diet that included some cow's milk-based products." *Id.* at ¶ 18. To state

[4] To the extent Plaintiffs' claim that Defendant Manufacturers' cow's milk-based products increased the risk of NEC in preterm and low-birth-weight infants, they still fail to plead sufficient facts to support this claim. The portions of the studies relied upon by Plaintiffs, taken as true at this juncture, show only that NEC can be more common in preterm and low-birth-weight infants fed cow's milk-based products than in those fed breast or donor milk. These studies do not show the cow's milk-based products **caused** any increase in risk. To the extent Plaintiffs' state the studies do reflect an increased risk of NEC in the infants, this is a legal conclusion without factual basis, which is impermissible under Pa. R. Civ. P. 1019 (see discussion *supra* at p. 19).

that preterm infants fed only breast milk are **less likely** to develop a form of NEC is to admit that NEC still develops in preterm infants **regardless of the diet.** Thus, Plaintiffs' second study likewise does not state that cow's milk-based feeding products cause NEC.

The third study cited by Plaintiffs concluded, per the Complaint, "fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death compared to fortification with a breast milk-based fortifier." *Id.* at ¶ 19. As Plaintiffs admitted in the Complaint, preterm and low-weight-birth infants are especially susceptible to NEC. Put another way, **these infants are already at an increased risk of NEC regardless of their diet.** This study, as described in Plaintiffs' Complaint, reflects this in explaining different rates of risk of developing NEC when using cow's milk-based or breast milk-based fortifiers. What the study does not state, as alleged in the Complaint, is that cow's milk-based fortifiers cause NEC.

The Surgeon General report cited by Plaintiffs is alleged in the Complaint to reiterate the principle made in the prior three studies and states that "formula feeding is associated with *higher rates*" of NEC in preterm infants and that "premature infants who are not breastfed are 138% more likely to develop NEC." *Id.* at ¶ 20 (emphasis added). If cow's milk-based formula caused NEC as Plaintiffs aver, one might expect the Surgeon General report to so state. Instead, the Surgeon General report, as described in Plaintiffs' Complaint at ¶ 20, makes the same acknowledgment as Plaintiffs – that preterm infants are highly susceptible to NEC regardless of their diet, and that NEC occurs in different rates in preterm infants fed cow's milk-based products and breast milk. The report does not state that the former causes NEC.

According to the Complaint, the American Academy of Pediatrics makes a nearly identical statement to the Surgeon General report. *Id.* at ¶ 21. The Academy makes a recommendation that

"all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized donor milk," which recommendation is alleged to be related in part to "lower rates… of NEC." *Id.* This statement acknowledges that NEC still occurs in preterm infants fed only breast milk, but simply at a lower rate. According to the Complaint, the Academy does not state that cow's milk-based feeding products cause NEC.

The fourth and fifth studies cited by Plaintiffs in their Complaint provide similar information. As alleged in the Complaint, a study "found that premature and low-birth-weight infants fed an exclusive breast-mild-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time." In another study, as alleged in the Complaint, "babies given exclusively breast milk products suffered NEC 5% of the time," whereas "babies given cow's milk products suffered NEC 17% of the time." *Id.* at ¶ 22-23. Once again, these studies, based on the allegations in Plaintiffs' Complaint, do not state that cow's milk-based formula causes NEC.

Ultimately, Plaintiffs' claim that Defendant Manufacturers' cow's milk-based feeding products cause NEC and are therefore unreasonably dangerous rests upon the notion that correlation equals causation. The numerous studies and reports cited by Plaintiffs in their Complaint purportedly show higher rates of NEC in preterm and low birth weight infants fed cow's milk-based diets than those fed breast milk, but this data exists in a world where Plaintiffs admit these infants are at a high risk of developing NEC regardless of diet. All that Plaintiffs' Complaint demonstrates, as pleaded under these facts, is that breast milk may be better at reducing that already high risk of NEC in these infants than cow's milk-based alternatives. This proposition does not make the Defendant Manufacturers' cow's milk-based alternatives unreasonably dangerous within

the meaning of § 388 of the Restatement (Second) of Torts and, accordingly, does not trigger a duty to warn on the part of Moving Defendants.

2. Moving Defendants Are Not a "Supplier" and, Therefore, Cannot Be Held Liable for Negligent Failure to Warn

Assuming *arguendo* that the Defendant Manufacturers' cow's milk-based feeding products can be seen as dangerous for their intended use as opposed to simply being a less effective alternative to breast milk products, Moving Defendants still had no duty to warn of the nature of cow's milk-based products under § 388 because they are not considered a supplier of cow's milk-based feeding products. Plaintiffs cite to no caselaw in Pennsylvania holding that a hospital is considered a supplier under § 388. Indeed, extensive research into this topic turns up no prior decisions where a Pennsylvania court has found a hospital to be a supplier in a products liability case for negligent failure to warn.

To determine a hospital may be defined as supplier of products ancillary to and following medical services within the meaning of § 388 would be to impose on the hospital a duty to warn about every conceivable object a patient may encounter in a hospital, right down to the napkins available in the hospital cafeteria. Imposing such a duty does nothing to advance the purpose of products liability law, i.e. to protect consumers from dangerous products in the stream of commerce. Moving Defendants are not in the best position to determine what products are available in the market for premature and low weight birth infants. In light of this, Plaintiffs have not sufficiently pleaded that Moving Defendants are a supplier under § 388.

For the foregoing reasons, Plaintiffs have not pleaded sufficient facts to aver the Defendant Manufacturers' products are unreasonably dangerous for their intended use and thus have not established Moving Defendants had a duty to warn. Alternatively, even if the products at issue here can be viewed as unreasonably dangerous, Plaintiffs still have failed to plead sufficient facts

that Moving Defendants are a supplier of products that are ancillary to the medical services provided to Plaintiffs. Accordingly, it is respectfully requested this Court sustain Moving Defendants' Preliminary Objections to Count VI: Failure to Warn of Plaintiffs' Complaint.

3. There is no Legal Basis for Plaintiffs to Present an Informed Consent Claim Regarding the Use of Cow's milk-based products

Plaintiffs' failure to warn claim is couched in language of product liability related to Moving Defendants' alleged duty "as a purchaser, supplier and/or distributor" to provide a product (cow's milk-based infant formula) that was free of unreasonable risk of harm to consumers (parents and their premature infants). This theory fails for the reasons stated above. However, to the extent that Plaintiffs are alleging that Moving Defendants, in providing medical care to Plaintiff-minor, failed to obtain Plaintiff-parent's consent to the use of cow's milk-based products and failed to warn of the purported risks and alternatives of such products, such a claim is also clearly precluded by Pennsylvania law.

Plaintiffs broadly allege that Moving Defendants failed to warn of the alleged dangers of cow's milk-based products and provide them with information necessary "to make an informed choice about whether to allow their baby to be fed the Defendant Manufacturers' products." *See* Exhibit "A" at ¶ 121. This purported failure to warn/inform allegedly led Plaintiff-minor to be fed a cow's milk-based product that Plaintiffs' contend caused and/or increased the risk of NEC. *Id.* at ¶ 125. The sole basis upon which Plaintiffs can proceed against Moving Defendants for "failure to warn" in the context of providing medical care is to assert such a claim under a theory of failure to obtain informed consent. Plaintiffs are impliedly asserting that Moving Defendants failed to obtain Plaintiff-parent's informed consent as to whether she should use cow's milk-based infant formula to feed her child as opposed to breastfeeding or using breast donor milk, based on the

alleged risks of cow's milk-based products. However, such a claim is not cognizable under Pennsylvania law.

Claims for informed consent in medical malpractice actions are governed by the Medical Care Availability and Reduction of Error Act, which provides as follows:

> (a) **Duty of Physicians**.--Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:
>
> (1) Performing surgery, including the related administration of anesthesia.
>
> (2) Administering radiation or chemotherapy.
>
> (3) Administering a blood transfusion.
>
> (4) Inserting a surgical device or appliance.
>
> (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.
>
> (b) Description of procedure.--Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted standards of medical practice would provide.

40 P.S. §1303.504 (emphasis added).

The clear language of the statute above reveals two significant tenets. The first is that the informed consent statute does not apply to the use of infant formula in feeding premature infants, since that is not a "procedure." Thus, there is no basis for Plaintiffs to contend that Plaintiff-parent's consent was required for the use of infant formula to feed her infant, including warning her of the risks or alternatives of same. Second, the informed consent statute only applies to

physicians, not hospitals, in the context of medical procedures. *See Morgan v. MacPhail*, 550 Pa. 202, 205 (1997).

Informed consent has not been extended to any type of therapeutic treatment involving an ingestible therapeutic drug, which the court defined as "an ongoing treatment upon examination by the treating physician, where any change of condition can be diagnosed and controlled." *Boyer v. Smith*, 345 Pa. Super. 66, 71, 497 A.2d 646, 648 (1985). The Superior Court ruled that the informed consent doctrine is premised upon the legal theory that the performance of a medical procedure without a patient's informed consent constitutes a technical assault or battery and that merely prescribing an oral medication does not involve a touching so not battery can occur and no informed consent is needed. *Id.* at 649. The same principles clearly apply to administration of infant formula to a newborn.

Further, an informed consent claim is only applicable to a physician and not the hospital and/or other health care entities. *See* 40 P.S. § 1303.504; *see also Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super. 1995) (holding that generally only the physician who performs the operation on the patient has the duty of obtaining his consent for the procedure). The Pennsylvania Supreme Court has held that informed consent involves the relationship between a physician and the patient and that the failure to obtain proper informed consent is deemed a battery, and the institution plays no role in the communications involved in obtaining the same. *See Valles v. Albert Einstein Medical Center*, 805 A.2d 1232 (2002). In *Valles*, the Court decisively ruled that:

> We find that a battery which results from a lack of informed consent is not the type of action that occurs within the scope of employment. In our view, a medical facility cannot maintain control over this aspect of the physician-patient relationship. Our lower courts have recognized that the duty to obtain informed consent belongs solely to the physician. (Citations omitted). Informed consent flows from the discussions each patient has with his physician, based on the facts and circumstances each case presents. We decline to interject an element of a hospital's control into this highly individualized and dynamic relationship. We agree with the

> lower court that to do so would be both improvident and unworkable. Thus, we hold that as a matter of law, a medical facility lacks the control over the manner in which the physician performs his duty to obtain informed consent so as to render the facility vicariously liable.

Id., 805 A.2d at 1239 (emphasis added). The *Valles* case remains the prevailing law in Pennsylvania. Pennsylvania courts have repeatedly applied this doctrine, recognizing and acknowledging that "[i]n a claim alleging lack of informed consent, it is the conduct of the unauthorized procedure that constitutes the tort." *Isaac v. Jameson Mem. Hosp.*, 932 A.2d 924, 929 (Pa. Super. 2007) (*citing Moure v. Raeuchle*, 604 A.2d 1003, 1008 (Pa. Super. 1992). Further, "[g]iven the unique nature of the doctrine and its origins as a technical battery, hospitals cannot be held vicariously liable for a physician's failure to obtain informed consent because 'a medical facility cannot maintain control over this aspect of the physician-patient relationship.'" *Isaac*, 932 A.2d at 930. As such, it is clear that the instant cause of action cannot be sustained against Moving Defendants as a matter of law.

B. DEMURRER TO COUNT VII: CORPORATE LIABILITY OF HEALTH CARE PROVIDER

1. Moving Defendants Cannot be Held Liable for Corporate Negligence Regarding a Food Product Which is Permitted for its Intended Use Pursuant to Federal Law

In *Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991), the Pennsylvania Supreme Court recognized the doctrine of corporate liability, holding that a hospital may be found directly liable for negligence if it fails to meet *any* of the following four duties: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.

Plaintiffs' corporate liability claim fails based on the same rationale as the claim for failure to warn. Both claims are based on the alleged failure to provide warnings to patients related to the use of cow's milk-based infant formula. As noted above, infant formula is regulated by the FDA, and there is no legal restriction on the use of cow's milk-based products for feeding of premature infants. Indeed, the Infant Formula Act expressly acknowledges that it is permissible to provide cow's-milk based products to low birth weight infants. Further, as discussed above, Plaintiffs cannot demonstrate that cow's milk-based formula is a dangerous product. Thus, there is no legal basis to contend that Moving Defendants can be held liable pursuant to a theory of corporate liability for failing to preclude the use of cow's milk-based products in the feeding of premature infants in the hospital.

Additionally, Courts considering the application of the duties set forth in *Thompson* have insisted on more than a simple finding of a negligent act by someone for whom the hospital is purportedly responsible. *Edwards v. Brandywine Hospital*, 652 A.2d 1382 (Pa. Super. 1995). In considering whether the plaintiff could sustain corporate negligence claims based on these allegations, the court analyzed the Thompson decision and delineated the standards required to sustain such a claim:

> The *Thompson* theory of corporate liability **will not be triggered every time something goes wrong in a hospital which harms a patient** . . . To establish corporate negligence, a plaintiff must show more than an act of negligence by an individual for whom the hospital is responsible. Rather, Thompson requires a plaintiff to show that the hospital itself is breaching a duty and is somehow substandard…*Thompson* contemplates a kind of '**systemic negligence**'…

Id. at 1386-87 (citations omitted and emphasis added). Thus, corporate liability requires "more than individual acts of negligence." *Id.* As noted by the court in *Edwards*, this reading of the Court's opinion in *Thompson* is the only way to logically construe its holding, as hospitals are already held vicariously liable for the negligent acts of their employees and ostensible agents, while "Thompson

requires a plaintiff to show that the **hospital itself** is breaching a duty and is somehow substandard." *Id*. at 1387; *see also MacDonald v. Chestnut Hill Hosp.*, 2005 Phila. Ct. Com. Pl. LEXIS 273, 18 (Pa. C.P. 2005) (granting nonsuit to the hospital defendant where "[t]here was no evidence that protocols were routinely ignored to the detriment of patients or that the kind of systematic negligence on the part of CHH required by the *Edwards* decision was present.")

Thus, a hospital may not be held liable via corporate negligence simply based on the alleged negligence of an individual health care provider. Accordingly, even if Plaintiffs could establish that the use of cow's milk-based infant formula was a breach of the standard of care by unidentified health care providers based on the specific circumstances of the Plaintiff-minor's case herein, which has not been pleaded by Plaintiffs considering the paucity of the allegations in the Complaint, such evidence cannot support a finding of corporate liability.

For the reasons stated above, Count VII of Plaintiffs' Complaint should be dismissed with prejudice.

2. Plaintiffs Are Precluded From Pursuing Corporate Negligence Claims as to The Trustees of the University of Pennsylvania

As noted *infra*, the Pennsylvania Supreme Court set forth certain nondelegable duties of hospitals, which if violated may support a finding of corporate negligence. The *Thompson* holding has been extended to HMO's and nursing home facilities, where it was determined that such entities performed similar functions as hospitals. *See Shannon v. Health America Pennsylvania, Inc.*, 718 A.2d 828 (Pa. Super. 1998); *Scampone v. Highland Park Care Center, LLC*, 57 A.3d 582 (Pa. 2012). However, courts have routinely refused to extend the *Thompson* holding past such institutions to cover other entities, such as medical clinics and physician practice groups. *See Sutherland v. Monongahela Valley Hospital*, 856 A.2d 55, 62 (Pa. Super. 2004); *Dowhouer v. Judson*, 45 Pa. D. & C.4th 172, 180 (Pa.Com.Pl. 2000); *Brewer v. Geisinger Clinic, Inc.*, 45 Pa. D.

& C.4th 215, 223 (Pa.Com.Pl. 2000); *Dibble v. Penn State Geisinger Clinic, Inc.*, 42 Pa. D. & C.4th 225 (Pa.Com.Pl. 1999); *Davis v. Gish*, 5 Pa. D. & C.5th 154, 159 (Pa.Com.Pl. 2007).

There is no legal basis for holding that the purported corporate parent of a hospital can be held liable under a theory of corporate negligence. The Trustees of the University of Pennsylvania is not a hospital and cannot be held liable under a theory of corporate liability, regardless of its relationship with Pennsylvania Hospital. Moreover, as Pennsylvania Courts have consistently held, corporate negligence duties are "non-delegable," i.e., only one entity can be held liable for a breach of these duties. The *Scampone* Court cautioned that the trial court should ensure that "multiple entities are not exposed to liability for breach of the same non-delegable duties." 57 A.2d at 606-07. Thus, even if a corporate negligence claim were permissible as to Pennsylvania Hospital, which is denied for the reasons stated above, The Trustees of the University of Pennsylvania, which is not a hospital, cannot also be exposed to liability for an alleged breach of the same, non-delegable duties arising out of the same factual allegations. Accordingly, even accepting as true all well pled facts in Plaintiffs' Complaint, the corporate negligence claims as to the non-hospital Defendant, the Trustees of the University of Pennsylvania, are legally insufficient and must therefore be dismissed.

C. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR INSUFFICIENT SPECIFICITY AS TO THE FACTS AND ALLEGED INJURIES

Pursuant to Pa.R.C.P. 1028(a)(3), a party may file preliminary objections in the nature of a motion to strike for insufficient specificity in a pleading. A plaintiff's Complaint is required to provide a defendant with notice of what the plaintiff's claims are and the grounds upon which they rest, and the complaint must also formulate the issues by summarizing the facts essential to support the claims. *Alpha Tau Omega Fraternity v. The University of Pennsylvania*, 464 A.2d 1349, 1352 (Pa. Super. 1983) (*citations omitted*). Pennsylvania Rule of Civil Procedure 1019(a) provides that

"the material facts on which a cause of action or defense is based shall be stated in a concise and summary form." Pa.R.C.P. 1019(a). As the Superior Court has noted,

> Rule 1019(a) requires fact pleading. The purpose of 1019(a) is to require the pleader to disclose the material facts sufficient to enable the adverse party to prepare his case. **A complaint therefore must do more than give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. It should formulate the issues by fully summarizing the material facts. Material facts are ultimate facts, i.e., those facts essential to support the claim. Evidence from which such facts may be inferred not only need not but should not be alleged. Allegations will withstand challenge under 1019(a) if (1) they contain averments of all of the facts a plaintiff will eventually have to prove in order to recover, and (2) they are sufficiently specific so as to enable defendant to prepare his defense.**

Baker v. Rangos, 324 A.2d 498, 505-506 (Pa. Super. 1974) (citations and internal quotations omitted)(emphasis added).

Further, it is well established that, with regard to the description of injuries sustained by a plaintiff, the Complaint must be stated with sufficient particularity to put the defendant on notice of evidence that may be produced at trial. *Kelly v. Martino*, 99 A.2d 901 (Pa. 1953). **A plaintiff's Complaint must set forth the extent, nature, location and duration of the injuries suffered, and injuries that are permanent should be stated specifically.** *Miller v. Perrige*, 71 Pa. D. & C.2d 476, 479–80 (Pa. Com. Pl. 1975). *See, also*, *Kopan v. Hawk*, 14 Pa. D. & C.2d 713, 714 (Pa. Com. Pl. 1958) ("A catchall averment of "other injuries" is nothing more than a generalized averment under which any injuries whatever could be proved at the trial. Defendant would have no knowledge in advance of the trial of what they are.")

Plaintiffs' Complaint is woefully deficient with regard to the specificity of the allegations of the relevant facts and injuries at issue in this case. Plaintiffs' description of the material facts relating to the minor's care and treatment, diagnosis and injuries is limited to four paragraphs, which are utterly insufficient to enable defendants to prepare their defenses. *See* Exhibit "A," ¶¶ 11-14. Plaintiffs aver that the minor was born prematurely but do not identify the gestational age

at which the child was born or her birth weight. Plaintiffs' allegation that "upon information and belief," the minor was fed Similac and/or Enfamil shortly after his birth (*Id.* at ¶ 12) does not comply with the fact-pleading requirements of Rule 1019(a), since such allegations do not provide Moving Defendants with appropriate notice of the facts as to whether the minor actually ingested cow's milk-based products. Further, plaintiffs have failed to identify which of the numerous products sold by Abbott and Mead Johnson under the Similac and Enfamil brand names were ingested by the minor. *Id.* at ¶¶ 37-38. Plaintiffs' Complaint further fails to provide a description of the material facts as to the period of time in which such products were ingested, when the minor was allegedly diagnosed with NEC and what treatment was provided for that condition.

The Complaint further fails to state the nature of the injuries and "long-term health effects" that are alleged to have resulted from the diagnosis of NEC. Plaintiffs' damages claim is not stated with particularity, is amorphous, vague, and open-ended. Pursuant to Pennsylvania pleading requirements, Moving Defendants should not be compelled to defend a claim for which the statement of injury is unspecified and subject to change.

In short, Plaintiffs' Complaint is inconsistent with the requirements of the Pennsylvania Rules of Civil Procedure as to the necessary specificity for the description of the facts and alleged injuries sustained. The facts in the Complaint are pleaded almost entirely "on information and belief." These omissions are fatal defects in Plaintiff's Complaint. Therefore, Plaintiffs' Complaint should be stricken in its entirety.

D. MOTION TO STRIKE PLAINTIFFS' CLAIMS FOR PUNITIVE DAMAGES

As in the other infant formula cases, In the *Ad Damnum* clauses of Counts VI and VII of the Complaint, Plaintiffs make baseless accusations that Moving Defendants engaged in oppressive, reckless, malicious and/or fraudulent conduct that allegedly justify an award of

punitive damages. *See* Exhibit "A," pp. 38, 46. However, the Complaint contains no specific allegations of conduct that would permit recovery of punitive damages as to Moving Defendants. Rather, Plaintiffs merely allege that "upon information and belief" H.S. may have been given a cow's milk-based infant formula following birth, absent any context to indicate that such an action was inappropriate based on the specific issues involved in H.S.'s medical care and condition following birth. For example, the Complaint gives no indication of whether Plaintiff-parent refused or was unable to provide breast milk and provides no information as to discussions between her and any health care providers regarding the purported use of cow's milk-based products.

Plaintiff's allegations of oppressive, malicious and similar conduct must be rejected as mere boilerplate. As discussed above, the FDA specifically approves the use of infant formula in care of low birth weight infants, with no restriction as to the use of cow's milk-based products for such infants. Indeed, the fact that Plaintiffs have filed numerous lawsuits against at least four hospitals in Philadelphia based on identical claims belies the contention that Moving Defendants engaged in outrageous or malicious conduct in allegedly feeding the Plaintiff-minor with cow's milk-based infant formula. Absent specific factual allegations to justify the claim that the use of infant formula in H.S.'s case was extreme and outrageous, there is no basis for an award of punitive damages in this case. Merely contending that punitive damages should be awarded with no supporting factual justification requires dismissal of this claim.

Since the purpose of punitive damages is not compensation of a plaintiff but punishment of the defendant and deterrence, punitive damages can be awarded only for conduct involving some element of outrage. *Hutchinson v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005). For that reason, Pennsylvania Supreme Court decisions establish that "punitive damages are an 'extreme remedy' available in only the most exceptional matters." *Wagner v. Onofrey*, 2006 Pa. Dist. & Cnty. Dec.

LEXIS 333, *11 (Pa. Com. Pl. 2006) (citing *Phillips v. Cricket Lighters*, 584 Pa. 179, 188, 883 A.2d 439, 445 (2005)). "In fact, punitive damages are specifically designed to heap an additional punishment on a defendant who is found to have acted in a fashion which is particularly egregious." *Wagner* at *12.

Punitive damages may not be awarded for misconduct that constitutes ordinary negligence such as inadvertence, mistake and errors of judgment. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985); *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 437 (Pa. Super. 1987). An award of punitive damages must be supported by evidence of conduct more serious than the mere commission of the underlying tort. *Allstate Ins. Co. v. A.M. Pugh Assoc., Inc.*, 604 F. Supp. 85, 99 (M.D. Pa. 1984).

Specifically, with regard to punitive damages in the context of claims against health care providers, the Medical Care and Reduction of Error (MCARE) Act permits punitive damages only to be awarded as follows:

> (a) Award. -- Punitive damages may be awarded for conduct that is the result of the health care provider's willful or wanton conduct or reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the health care provider's act, the nature and extent of the harm to the patient that the health care provider caused or intended to cause and the wealth of the health care provider.
>
> (b) Gross Negligence. -- A showing of gross negligence is insufficient to support an award of punitive damages.

41 P.S. §1303.505.

The Supreme Court has made clear that when assessing the propriety of the imposition of punitive damages, "the state of mind of the actor is vital. The act or failure to act, must be intentional, reckless or malicious." *Hutchinson, supra* at 770. An appreciation of the risk is a necessary element of the mental state required for the imposition of punitive damages. *Id.* at 772.

Thus, "a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk." *Id.*

Since professional negligence actions involve allegations that health care professionals deviated from the governing standard of care, punitive damages are generally not recoverable in malpractice actions unless the medical provider's deviation from the applicable standard of care is so egregious as to evince a conscious or reckless disregard of a patent risk of harm to the patient. *Wagner*, *supra*.

Where the facts as averred show nothing more than negligence, a lapse in judgment, or mere inadvertence, courts in Pennsylvania have dismissed pleas and claims for punitive damages, often at the pleadings stage of litigation and even if the complaint alleged severe injuries or death. *See*, *e.g.*, *Brownawell v. Bryan*, 40 Pa. D. & C.3d 604, 606 (Pa. Com. Pl. 1985) (dismissing punitive damages claim where a plaintiff alleged that a physician negligently performed a spinal fusion surgery that left the plaintiff with severe neurological defects, and noting that "**the mere pleading of outrageous conduct** does not, of course, satisfy the requirement stating facts which, if proven, would form a basis for a jury concluding that the conduct was such that an award of punitive damages was warranted.") (emphasis added); *Wagner*, *supra* at *11 (contentions that physician failed to prescribe antibiotics, order certain tests or request an infectious disease consult constituted "nothing more than ordinary negligence and are insufficient to support an award of punitive damages."); *McCardle v. Aldinger*, 5 Pa. D. & C.4th 421, 428 (Pa. Com. Pl. 1996) (sustaining preliminary objections and dismissing claim for punitive damages where the plaintiff alleged negligence in the prenatal care of her child that led to the child was stillborn and holding that "[i]t is not the outcome of the alleged negligence that is of consideration, but rather the alleged conduct

of defendants that is at issue."); *Flurer v. Pocono Medical Ctr.*, 15 Pa. D. & C.4th 645, 670 (Pa. Com. Pl. 1992) (sustaining preliminary objections and finding that plaintiffs were not "capable of pleading the requisite behavior" for an award of punitive damages where a hospital allegedly failed to properly utilize a fetal monitor on a pregnant woman who was involved in a serious car accident and thereafter delivered a stillborn child).

Conversely, punitive damages have been reserved for those situations that are truly egregious and utterly outrageous, and typically involve aggravating or other factors that evince a particularly reckless mind or evil motive. *See, e.g.*, *Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3rd Cir. 1987) (anesthesiologist who abandoned patient on operating room table and left room for a lunch break without securing a suitable replacement could be liable for punitive damages to patient who suffered irreversible paralysis from anesthesia complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492 A.2d 1382, 386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed Guillain-Barre Syndrome patient suffering from neurological paralysis to remain crying and immobile on floor for two hours as physician repeatedly stepped over patient was sufficient to support punitive damages claim); *Guernsey v. County Living Personal Care Home, Inc.*, 2006 U.S. Dist. LEXIS 31450, 2006 WL 1412765 (M.D. Pa. 2006) (punitive damages recoverable from nursing home officials who allowed resident to have access to room of 86-year old Alzheimer's patient where he repeatedly raped her, since nursing home was aware of resident's prior criminal convictions for sex registration as a sexual offender under Megan's Law, and his prior instances of grabbing and kissing staff); *Lawrence v. Kunkle*, 75 D. & C. 4th 370 (Pa. Com. Pl. 2005) (patient could maintain punitive damages claim against physician who refused to perform emergency surgery because patient did not have medical

insurance even though physician knew that patient would likely suffer permanent neurologic and functional deficits if surgery was delayed).

All of the cases in the paragraph above set forth examples of egregious conduct, completely inapposite to the facts of the instant case. The facts underlying Plaintiffs' bare assertions of reckless, outrageous or similar behavior do not even remotely meet the requisite standard under Pennsylvania law that would permit an award of punitive damages. Even assuming the allegations in the Complaint were true for the purposes of this argument only, the outcome in this case was not the result of any intentional wrongdoing or deliberate misconduct on the part of Moving Defendants or any medical provider at Pennsylvania Hospital, nor does the Complaint contain any such allegations.

Additionally, pursuant to § 505(c) of the MCARE Act, punitive damages are specifically restricted in claims involving vicarious liability:

> (c) Vicarious liability. -- Punitive damages shall not be awarded against a healthcare provider who is only vicariously liable for the actions of its agent that caused the injury unless it can be shown by a preponderance of the evidence that the party knew of and allowed the conduct of its agent that resulted in an award of punitive damages.

40 P.S. §1303.505(c). Plaintiffs allege in this action that unidentified "staff" fed H.S. Similac and/or Enfamil at Pennsylvania Hospital shortly after her birth and failed to warn Plaintiff-parent of the alleged risks of such products. See Exhibit "A," ¶ 12. Even if such actions were claimed to be egregious or malicious such that punitive damages were permissible, which is denied for the reasons stated above, Plaintiffs must allege facts to establish that Moving Defendants had actual knowledge of the alleged wrongful conduct and nevertheless allowed it. *See Zazzera v. Roche*, 54 D. & C. 4th 225, 238 (Pa. Com. Pl. 2001); *Dean Witter Reynolds, Inc. v. Genteel*, 499 A.2d 637 (Pa. Super. 1985). In this matter, Plaintiffs have failed to plead any facts to suggest that Moving

Defendants were aware of any alleged misconduct by any individual alleged to be an agent and allowed such conduct to continue.

For all these reasons, Plaintiffs' demand for punitive damages must be stricken with prejudice as to Moving Defendants, along with all allegations of reckless and similar conduct.

E. MOTION TO DISMISS PLAINTIFF-PARENT'S CLAIMS

1. Plaintiff-Parent has Failed to State a Cause of Action

Plaintiff-parent seeks to recover damages in her own right and as the parent and natural guardian of H.S. Plaintiffs' Complaint includes allegations in each count asserted as to Moving Defendants in which it is averred that Plaintiff-parent "suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly altered by the Injured Infant's injuries." *See* Exhibit "A," ¶¶ 126, 139 and 147. However, no specific cause of action is asserted as to any damages sought by Plaintiff-parent in her own right, who is not alleged in the Complaint to have suffered any physical injuries as a result of the alleged negligent conduct of Moving Defendants. For this reason, Plaintiff-parent's claim should be dismissed.

2. Plaintiffs are Required to Plead Separate Claims Pursuant to Pa.R.C.P. 1020

Further, even if Plaintiff-parent had properly articulated a cause of action in the Complaint to allow her to recover damages in her own right, the Complaint should be stricken pursuant to Pa.R.C.P. 1020(b), which provides as follows:

> If persons join as plaintiffs under Rules 2228, 2229(a) or (e), the complaint shall state the cause of action, any special damage, and the demand for relief of each plaintiff in a separate count, preceded by a heading naming the parties to the causes of action therein set forth.

Accordingly, it is improper for Plaintiffs to plead in a single count claims on behalf of both the Plaintiff-minor and the Plaintiff-parent, as was done in the Complaint filed herein. Claims on

behalf of each of the Plaintiffs must be set forth in separate counts of the Complaint, specifically identifying the cause of action asserted and relief sought in each count.

3. Plaintiff-Parent's Claim Is Precluded Pursuant to the Statute of Limitations

Although the statute of limitations for claims asserted on behalf of minors are tolled until the age of majority, Plaintiff-parent's claims were not similarly tolled and were required to have been brought within two years of the alleged injury. *See Hathi v. Krewstown Park Apts,* 561 A.2d 1261 (Pa. Super. 1989); 42 Pa.C.S. § 5524. Plaintiffs allege that H.S. was born on September 12, 2006, was fed the Defendant manufacturers' products shortly after her birth, and developed NEC shortly thereafter. *See* Exhibit "A," ¶¶ 11-13. Thus, since the Complaint herein was filed on March 24, 2022, Plaintiff-parent's claims herein are clearly time-barred based on the applicable statute of limitations.

F. MOTION TO STRIKE PLAINTIFFS' COMPLAINT FOR FAILURE TO COMPLY WITH Pa.R.C.P. 1024

Pennsylvania Rule of Civil Procedure 1024(a) requires verification of every pleading containing a factual averment based upon the signer's personal knowledge or information and belief. Rule 1024(c) requires that the verification be made by one or more of the parties filing the pleading. In this case, Plaintiffs' counsel signed the verification for the Complaint, in violation of Rule 1024. *See* Exhibit "A." Accordingly, the Complaint should be stricken for lack of an appropriate verification.

V, REQUESTED RELIEF

For the foregoing reasons, Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine respectfully request that this Honorable Court sustain their Preliminary Objections and enter the attached Order.

BURNS WHITE LLC

BY: 

JAMES A. YOUNG, ESQ.
RICHARD S. MARGULIES, ESQ.
Attorneys for Defendants,
The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine

CERTIFICATE OF SERVICE

I, Richard S. Margulies, Esquire, do hereby certify that on this day I caused a true and correct copy of the foregoing Preliminary Objections of Defendants The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital and The Trustees of the University of Pennsylvania d/b/a Penn Medicine to Plaintiffs' Complaint, to be served via electronic filing, to the following counsel of record, addressed as follows:

Tracy Finken, Esq.
Anapol Weiss
One Logan Square
130 N. 18th Street, Suite 1600
Philadelphia, PA 19103

Ashley Keller, Esquire
Keller Lenkner, LLC
150 N. Riverside Plaza, Suite 4100
Chicago, IL 60606

Alex Walsh, Esquire
Walsh Law PLLC
1050 Connecticut Avenue, NW, Suite 500
Washington, D.C. 20036

BY: 
RICHARD S. MARGULIES, ESQ.

Dated: April 19, 2022

EXHIBIT A

ANAPOL WEISS
BY: TRACY FINKEN, ESQUIRE
Identification Number: 82258
One Logan Square
130 N. 18th Street, Suite 1600
Philadelphia, PA 19103
(215) 735-0773
tfinken@anapolweiss.com

ATTORNEY FOR PLAINTIFFS

KELLER LENKNER LLC
BY: Ashley Keller (*pro hac vice forthcoming*)
150 N. Riverside Plaza, Suite 4100
Chicago, Illinois 60606
Telephone: (312) 741-5220
Fax: (312) 971-3502
Email: ack@kellerlenkner.com

ATTORNEY FOR PLAINTIFFS

WALSH LAW PLLC
BY: Alex Walsh (*pro hac vice forthcoming*)
1050 Connecticut Ave, NW, Suite 500
Washington, D.C. 20036
Telephone: (202) 780-4127
Fax: (202) 780-3678
Email: awalsh@alexwalshlaw.com

ATTORNEY FOR PLAINTIFFS

TERRAINE ABDULLAH, on her own Behalf and as Parent and Natural Guardian of H.S., a Minor 335 Passmore Street Philadelphia, PA 19111 Plaintiffs	:	COURT OF COMMON PLEAS PHILADELPHIA COUNTY
v.	:	CIVIL ACTION
MEAD JOHNSON & COMPANY, LLC Illinois Corporation Service Co. 801 Adlai Stevenson Drive Springfield, IL 62703	:	NO.
MEAD JOHNSON NUTRITION COMPANY Illinois Corporation Service Co. 801 Adlai Stevenson Drive Springfield, IL 62703	:	
ABBOTT LABORATORIES	:	

CT Corporation System
208 So. Lasalle Street, Suite 814
Chicago, IL 60604

THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM d/b/a PENNSYLVANIA HOSPITAL
3400 Civic Center Blvd.
Philadelphia, PA 19104

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA d/b/a PENN MEDICINE
133 South 36th Street
Philadelphia, PA 19104

Defendants : **JURY TRIAL DEMANDED**

COMPLAINT IN CIVIL ACTION

NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA BAR ASSOCIATION
LAWYER REFERRAL AND INFORMATION SERVICE
ONE READING CENTER
PHILADELPHIA, PA 19107
TELEPHONE: (215) 238-1701

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas las páginas siguientes, usted tiene viente (20) dias de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puese perder dinero o sus propiedades u ostros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO IMMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICO, VAYA EN PERSONA O LLAME POR TELEPHONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ASOCIACION DE LICENCIADOS DE FILADELFIA
Servicio De Referencia E Información Legal
One Reading Center
Filadelfia, Pennsylvania 19107
Telephono: (215) 238-1701

ANAPOL WEISS
BY: TRACY FINKEN, ESQUIRE
IDENTIFICATION NUMBER: 82258
ONE LOGAN SQUARE
130 N. 18TH STREET, SUITE 1600
PHILADELPHIA, PA 19103
(215) 735-0773
TFINKEN@ANAPOLWEISS.COM

ATTORNEY FOR PLAINTIFFS

KELLER LENKNER LLC
BY: ASHLEY KELLER (*PRO HAC VICE FORTHCOMING*)
150 N. RIVERSIDE PLAZA, SUITE 4100
CHICAGO, ILLINOIS 60606
TELEPHONE: (312) 741-5220
FAX: (312) 971-3502
EMAIL: ACK@KELLERLENKNER.COM

ATTORNEY FOR PLAINTIFFS

WALSH LAW PLLC
BY: ALEX WALSH (*PRO HAC VICE FORTHCOMING*)
1050 CONNECTICUT AVE, NW, SUITE 500
WASHINGTON, D.C. 20036
TELEPHONE: (202) 780-4127
FAX: (202) 780-3678
EMAIL: AWALSH@ALEXWALSHLAW.COM

ATTORNEY FOR PLAINTIFFS

TERRAINE ABDULLAH, ON HER OWN BEHALF AND AS PARENT AND NATURAL GUARDIAN OF H.S., A MINOR 335 PASSMORE STREET PHILADELPHIA, PA 19111 PLAINTIFFS V. MEAD JOHNSON & COMPANY, LLC ILLINOIS CORPORATION SERVICE CO. 801 ADLAI STEVENSON DRIVE SPRINGFIELD, IL 62703 MEAD JOHNSON NUTRITION COMPANY ILLINOIS CORPORATION SERVICE CO. 801 ADLAI STEVENSON DRIVE SPRINGFIELD, IL 62703 ABBOTT LABORATORIES CT CORPORATION SYSTEM 208 SO. LASALLE STREET, SUITE 814 CHICAGO, IL 60604 THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM D/B/A PENNSYLVANIA	COURT OF COMMON PLEAS PHILADELPHIA COUNTY CIVIL ACTION NO.

HOSPITAL **3400 CIVIC CENTER BLVD.** **PHILADELPHIA, PA 19104**	:	
THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA D/B/A PENN MEDICINE **133 SOUTH 36TH STREET** **PHILADELPHIA, PA 19104**	:	
DEFENDANTS	:	**JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff brings this Complaint and Demand for Jury Trial (the "Complaint") against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories (collectively "the Defendant Manufacturers"), and The Trustees of the University of Pennsylvania d/b/a Penn Medicine and Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively "Penn Medicine" or "Pennsylvania Hospital"), together "Defendants." Plaintiff alleges the following upon personal knowledge as to Plaintiff's own acts and experiences and upon information and belief, including investigation conducted by Plaintiff's attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the "Injured Infant") who was given the Defendant Manufacturers' cow's milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers' products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis ("NEC"), a life-altering and potentially deadly disease that largely affects premature babies who are given cow's milk-based feeding products. As a result,

the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent ("the Plaintiff Parent").

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant's consumption of the Defendant Manufacturers' unreasonably dangerous cow's milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Terraine Abdullah is a natural adult person and a resident of Pennsylvania. Ms. Abdullah is the parent and natural guardian of H.S., a minor. Ms. Abdullah's address is 335 Passmore Street, Philadelphia, Pennsylvania 19111.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, "Mead") are manufacturers of cow's milk-based infant feeding products and market many of these products under the "Enfamil" brand name.

5. Defendant Abbott Laboratories ("Abbott") is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow's milk-based infant feeding products and markets many of its products under the "Similac" brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of $50,000.

IV. FACTUAL ALLEGATIONS

H.S.'s NEC Diagnosis

11. H.S. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 12, 2006.

12. Upon information and belief H.S. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after her birth.

13. Upon information and belief shortly after H.S. first ingested the Defendant Manufacturers' products, she developed NEC.

14. H.S. was forced to undergo surgery and has continued to suffer long term health effects.

Cow's Milk-Based Feeding Products Are Known to Cause NEC

15. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

16. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

17. For example, in one randomized, multicenter study of 926 preterm infants, NEC was six to ten times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was 20 times more common in those only fed cow's milk formula than in those fed breast milk.

18. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

19. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

20. A Surgeon General report, The Surgeon General's Call to Action to Support Breastfeeding, warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are 138% more likely to develop NEC.

21. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults," has advised that all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based on the "potent benefits of human milk," including "lower rates of . . . NEC."

22. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time.

23. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives To Cow's Milk-Based Products Exist

24. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

25. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

26. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

27. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

28. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

29. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge.

The Defendant Manufacturers' False And Misleading Marketing Regarding Cow's Milk-Based Infant Products

30. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

31. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

32. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

33. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message, with one study estimating that formula manufacturers collectively spent $4.48 billion on marketing and promotion in 2014 alone.

34. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

35. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

36. For example, Abbott's website, on a paged titled "Infant Formula Marketing," states: "We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

37. Abbott markets and sells multiple products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

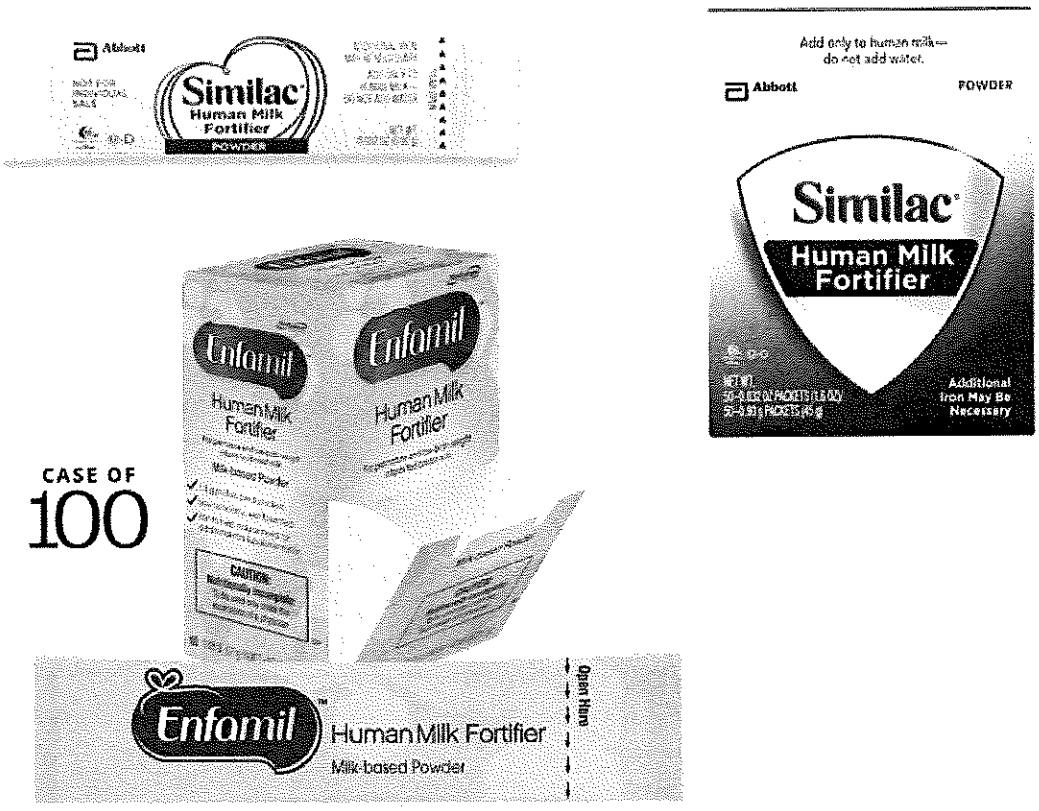
38. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: "Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants" and noted that Enfamil formulas include "expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development."

39. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in the advertisement, including in such statements as "for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk" and "only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk." The webpage for the product has made similar manipulative claims, stating "Enfamil is backed by decades of breast milk research and multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]"

40. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants' discharge from the NICU or hospital.

41. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

42. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:



43. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

The Defendant Manufacturers' Inadequate Warnings

44. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

45. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

46. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

47. Mead cites no medical literature or research to guide the use of its products.

48. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

49. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

50. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

51. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

52. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

53. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

54. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

55. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

56. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of those

dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

57. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience "changing hospital systems and influencing policy," and its findings were unequivocal:

> This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that "[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC)."

58. Penn Medicine also purports to adhere to the tenets of the "Baby Friendly Hospital Initiative," which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The "Baby Friendly Hospital Initiative" specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its "Baby Friendly" designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

59. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers' cow's milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

> Donor milk is not inexpensive. It costs about $4.25 per ounce, but the return on investment is huge. "Preemies given mother's milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis," Carpenter said, adding that the infection can cost up to $250,000 to treat. The average cost to provide a preemie with donor milk: $125.

60. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers' products.

61. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers' products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

62. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategy, which aims to "sell and service" healthcare professionals and medical staff as a means of converting them into "extra salespersons."

Safer Alternative Designs

63. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

64. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

65. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION

COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

66. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

67. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

68. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

69. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

70. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

71. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

72. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

73. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

74. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

75. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)

76. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

77. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of

their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

78. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

79. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or

b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failed to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or

e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or

h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

80. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

81. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused and/or increased risk of their developing NEC.

82. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the

Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

83. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT III: NEGLIGENCE
(Against Abbott and Mead)

84. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

85. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

86. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

87. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

88. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or

b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or

e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or

h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

89. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

90. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

91. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

92. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)

93. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

94. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

95. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

96. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

97. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That cow's milk-based products were safe for premature infants; and/or

e. That cow's milk-based products were necessary for optimum growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

98. Abbott and Mead knew or reasonably should have known those misrepresentations to be false.

99. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.

100. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional

misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

101. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

102. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT V: NEGLIGENT MISREPRESENTATION
(Against Abbott and Mead)

103. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

104. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

105. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

106. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

107. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That cow's milk-based products were safe for premature infants; and/or

e. That cow's milk-based products were necessary for optimum growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

108. Abbott and Mead were negligent or careless in not determining those representations to be false.

109. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

110. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent

misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

111. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

112. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)

113. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

114. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

115. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

116. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

117. Penn Medicine and Pennsylvania Hospital negligently and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

118. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives

an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

119. Penn Medicine and Pennsylvania also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

120. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

121. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or

b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or

f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or

g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

122. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

123. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

124. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

125. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

126. As a further direct and proximate result of Penn Medicine and Pennsylvania failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, reckless, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)

127. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

128. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

129. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

130. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

131. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute,

and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

132. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

133. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

134. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

135. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or

b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or

c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or

g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to

Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or

h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

136. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

137. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

138. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

139. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent and reckless conduct the Plaintiff Parent suffered significant emotional distress, loss of

income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

140. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

141. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

142. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or

b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or

c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or

e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice

about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or

h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or

i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

143. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

144. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

145. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

146. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

147. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, , the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;

Case ID: 220302583
Control No.: 22043304

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

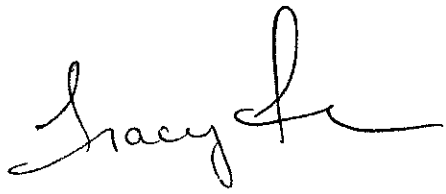
DEMAND FOR JURY TRIAL

148. Plaintiff hereby demands a jury trial for all claims triable.

Dated: March 24, 2022

Respectfully submitted,

ANAPOL WEISS



Tracy Finken
130 N. 18th Street, Suite 1600
Philadelphia, PA 19103
Phone: (215) 735-1130
Email: tfinken@anapolweiss.com

KELLER LENKNER LLC
Ashley Keller (*pro hac vice forthcoming*)
150 N. Riverside Plaza, Suite 4100
Chicago, Illinois 60606

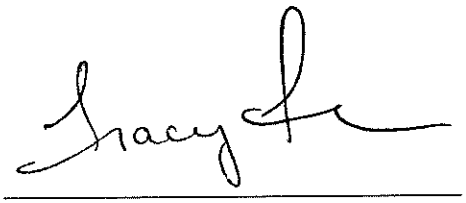
Telephone: (312) 741-5220
Fax: (312) 971-3502
Email: ack@kellerlenkner.com

WALSH LAW PLLC
Alex Walsh (*pro hac vice forthcoming*)
1050 Connecticut Ave, NW, Suite 500
Washington, D.C. 20036
Telephone: (202) 780-4127
Fax: (202) 780-3678
Email: awalsh@alexwalshlaw.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

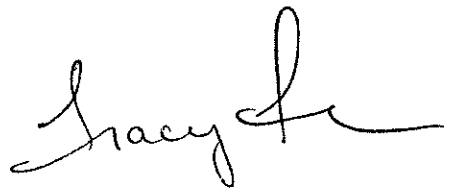
I hereby certify that on March 24, 2022, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.



Tracy Finken

VERIFICATION

I, the undersigned, Tracy Finken, verify that the statements made in this document are true and correct to the best of my knowledge, information, and belief. I understand that false statements herein are made subject to the penalties of 18 Pa. C.S. §4904, relating to unsworn falsification to authorities.



Date: March 24, 2022

Tracy Finken

EXHIBIT A-5

ANAPOL WEISS
BY: TRACY FINKEN, ESQUIRE
Identification Number: 82258
One Logan Square
130 N. 18th Street, Suite 1600
Philadelphia, PA 19103
(215) 735-0773
Email: tfinken@anapolweiss.com

ATTORNEY FOR PLAINTIFFS

Keller Lenkner LLC
BY: Ashley Keller (pro hac vice forthcoming)
150 N. Riverside Plaza, Suite 4100
Chicago, Illinois 60606
Telephone: (312) 741-5220
Fax: (312) 971-3502
Email: ack@kellerlenkner.com

ATTORNEY FOR PLAINTIFFS

Walsh Law PLLC
BY: Alex Walsh (pro hac vice forthcoming)
1050 Connecticut Ave, NW, Suite 500
Washington, D.C. 20036
Telephone: (202) 780-4127
Fax: (202) 780-3678
Email: awalsh@alexwalshlaw.com

ATTORNEY FOR PLAINTIFFS

TERRAINE ABDULLAH, on her own behalf and as Parent and Natural Guardian of H.S., a Minor,	:	**COURT OF COMMON PLEAS PHILADELPHIA COUNTY**
Plaintiffs	:	
v.	:	**CIVIL ACTION**
MEAD JOHNSON & COMPANY, LLC, et al.	:	**NO.: 220302583**
Defendants.	:	

AFFIDAVIT OF SERVICE

COMMONWEALTH OF PENNSYLVANIA)
COUNTY OF PHILADELPHIA)

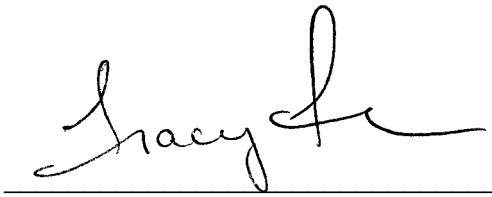
TRACY FINKEN, ESQUIRE, being duly sworn according to law, deposes and says that she is the attorney for the Plaintiff above named action and that the facts set forth in the Affidavit as set forth below are true and correct to the best of her knowledge, information and belief.

1. On March 24, 2022, a Civil Action Complaint was filed in the above matter in the Court of Common Pleas of Philadelphia County, Pennsylvania.

2. On or around April 15, 2022, Defendants, Mead Johnson & Company, LLC and Mead Johnson Nutrition Company, were served with a true and correct copy of the Complaint in this matter by certified mail, return receipt requested #7020 1810 0002 1257 5326 and #7020

1810 0002 1257 5333. A true and correct copy of the transmittal letter as well as the return receipt is attached hereto.

3. I hereby state that I am the attorney for the within named Plaintiff and the facts set forth in the foregoing Affidavit, are true and correct to the best of my knowledge, information and belief; and this statement is made subject to the penalties of 18 Pa. C.S.A. Sec. 4904 relating to unsworn falsification to authorities.



TRACY FINKEN, ESQUIRE

ANAPOLWEISS

Tracy A. Finken, Esquire
One Logan Square
130 N. 18th Street, Suite 1600
Philadelphia PA 19103
tfinken@anapolweiss.com

(215) 735-0773 Direct Dial
(215) 875-7731 Direct Fax

April 8, 2022

Mead Johnson Nutrition Company
Illinois Corporation Service C
801 Adlai Stevenson Drive
Springfield, IL 62703

Re: Service of Summons and Complaints

Dear Sir/Madam:

Enclosed please find a true and correct copy of the following Plaintiffs' Summons and Complaints, the originals of which were filed of record in the Philadelphia Court of Common Pleas on March 24, 2022, relative to the above-captioned matter:

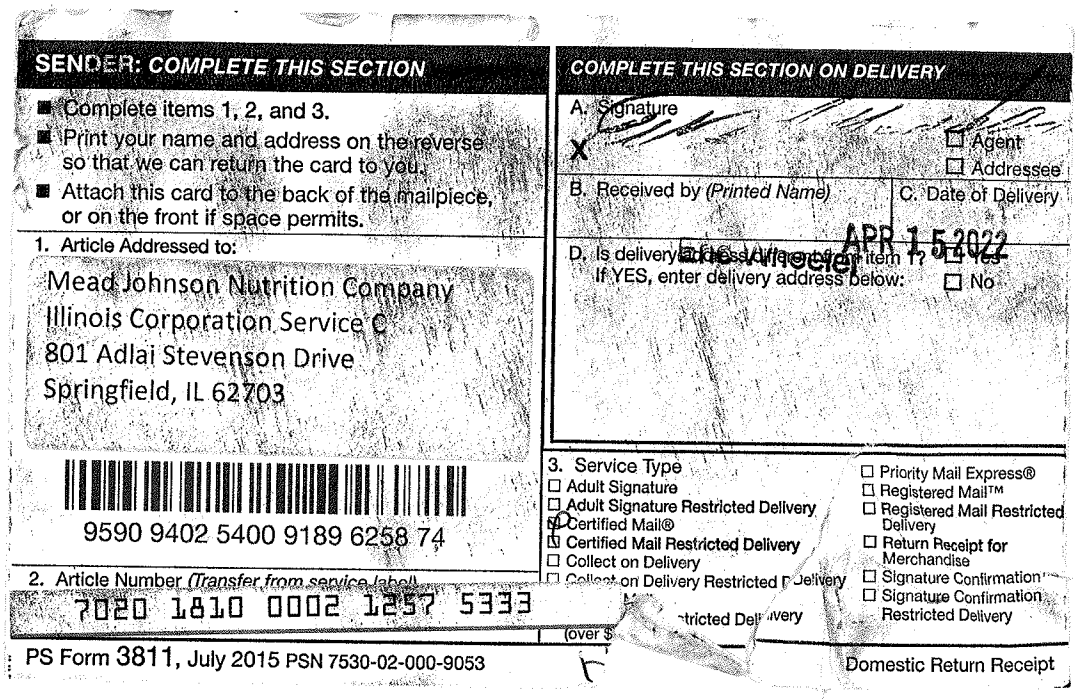
1. Terraine Abdullah, et al. v. Mead Johnson Company, et al., Civil Action No. 220302583;
2. Holli Carter, et al. v. Mead Johnson Company, et al., Civil Action No. 220302588;
3. Shondera Drayton, et al . v. Mead Johnson Company, et al., Civil Action No. 220302594;
4. Alice Stills, et al. v. Mead Johnson Company, et al., Civil Action No.220302617;
5. Christina Taylor, et al. v. Mead Johnson Company, et al., Civil Action No.220302606;
6. Gina Wieger, et al. v. Mead Johnson Company, et al., Civil Action No. 220302614;
7. Gina Wieger, et al, v. Mead Johnson Company, et al., Civil Action No. 220302601

Plaintiff shall deem this case served upon your receipt of the enclosed Summons and Complaints. Please respond to the enclosed pursuant to the allotted time required under Pennsylvania law.

Very truly yours,

TRACY A. FINKEN

TAF/nsg
Enclosures
Via Certified Mail/Return Receipt Requested: 7020 1810 0002 1257 5333



SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Mead Johnson Nutrition Company
Illinois Corporation Service C
801 Adlai Stevenson Drive
Springfield, IL 62703

9590 9402 5400 9189 6258 74

2. Article Number *(Transfer from service label)*

7020 1810 0002 1257 5333

PS Form 3811, July 2015 PSN 7530-02-000-9053

COMPLETE THIS SECTION ON DELIVERY

A. Signature

X

☐ Agent
☐ Addressee

B. Received by *(Printed Name)*

C. Date of Delivery

APR 15 2022

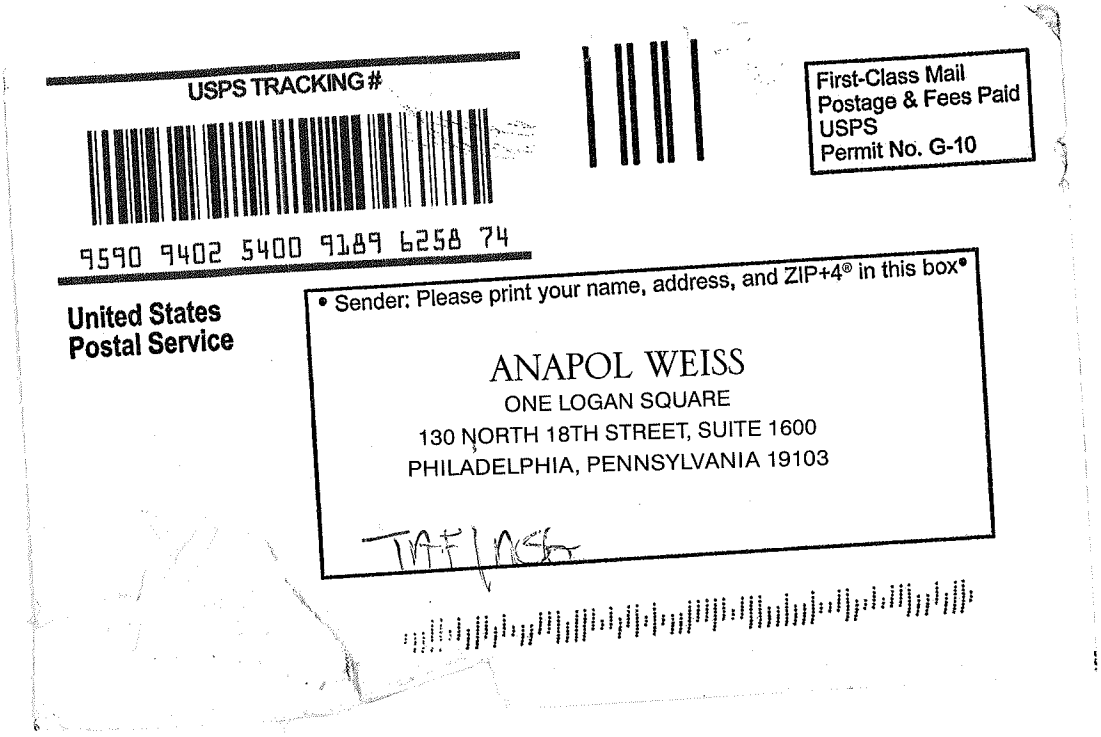
D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type

☐ Adult Signature
☐ Adult Signature Restricted Delivery
☑ Certified Mail®
☑ Certified Mail Restricted Delivery
☐ Collect on Delivery
☐ Collect on Delivery Restricted Delivery
☐ Priority Mail Express®
☐ Registered Mail™
☐ Registered Mail Restricted Delivery
☐ Return Receipt for Merchandise
☐ Signature Confirmation™
☐ Signature Confirmation Restricted Delivery

(over $

Domestic Return Receipt


USPS TRACKING #
9590 9402 5400 9189 6258 74
First-Class Mail
Postage & Fees Paid
USPS
Permit No. G-10
United States
Postal Service
• Sender: Please print your name, address, and ZIP+4® in this box•
ANAPOL WEISS
ONE LOGAN SQUARE
130 NORTH 18TH STREET, SUITE 1600
PHILADELPHIA, PENNSYLVANIA 19103

ANAPOLWEISS

Tracy A. Finken, Esquire
One Logan Square
130 N. 18th Street, Suite 1600
Philadelphia PA 19103
tfinken@anapolweiss.com

(215) 735-0773 Direct Dial
(215) 875-7731 Direct Fax

April 8, 2022

Mead Johnson & Company, LLC
Illinois Corporation Service C
801 Ablai Stevenson Drive
Springfield, IL 62703

Re: Service of Summons and Complaints

Dear Sir/Madam:

Enclosed please find a true and correct copy of the following Plaintiffs' Summons and Complaints, the originals of which were filed of record in the Philadelphia Court of Common Pleas on March 24, 2022, relative to the above-captioned matter:

1. Terraine Abdullah, et al. v. Mead Johnson Company, et al., Civil Action No. 220302583;
2. Holli Carter, et al. v. Mead Johnson Company, et al., Civil Action No. 220302588;
3. Shondera Drayton, et al . v. Mead Johnson Company, et al., Civil Action No. 220302594;
4. Alice Stills, et al. v. Mead Johnson Company, et al., Civil Action No.220302617;
5. Christina Taylor, et al. v. Mead Johnson Company, et al., Civil Action No.220302606;
6. Gina Wieger, et al. v. Mead Johnson Company, et al., Civil Action No. 220302614;
7. Gina Wieger, et al, v. Mead Johnson Company, et al., Civil Action No. 220302601

Plaintiff shall deem this case served upon your receipt of the enclosed Summons and Complaints. Please respond to the enclosed pursuant to the allotted time required under Pennsylvania law.

Very truly yours,

TRACY A. FINKEN

TAF/nsg
Enclosures
Via Certified Mail/Return Receipt Requested: 7020 1810 0002 1257 5326

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Mead Johnson & Company, LLC
Illinois Corporation Service C
801 Adlai Stevenson Drive
Springfield, IL 62703

9590 9402 5400 9189 6258 81

2. Article Number *(Transfer from service label)*
7020 1810 0002 1257 5326

COMPLETE THIS SECTION ON DELIVERY

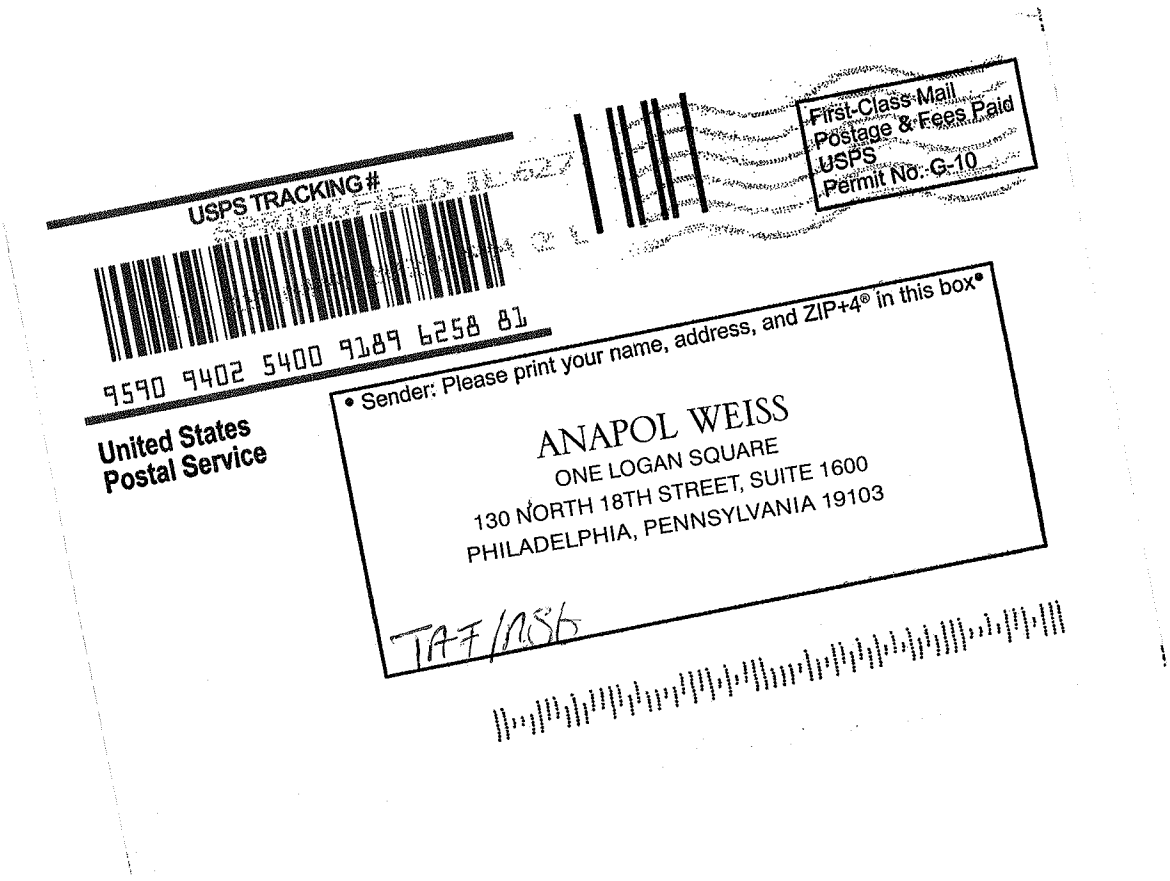
A. Signature
X
☒ Agent
☐ Addressee

B. Received by *(Printed Name)* Eric Wheeler
C. Date of Delivery APR 1 5 2022

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☐ Adult Signature
☐ Adult Signature Restricted Delivery
☒ Certified Mail®
☐ Certified Mail Restricted Delivery
☐ Collect on Delivery
☐ Collect on Delivery Restricted Delivery
☐ Insured Mail
Mail Restricted Delivery
00)
☐ Priority Mail Express®
☐ Registered Mail™
☐ Registered Mail Restricted Delivery
☐ Return Receipt for Merchandise
☐ Signature Confirmation™
☐ Signature Confirmation Restricted Delivery

PS Form 3811, July 2015 PSN 7530-02-000-9053 1 of 2 UP Domestic Return Receipt


USPS TRACKING #
9590 9402 5400 9189 6258 87
First-Class Mail
Postage & Fees Paid
USPS
Permit No. G-10
United States
Postal Service
• Sender: Please print your name, address, and ZIP+4® in this box•
ANAPOL WEISS
ONE LOGAN SQUARE
130 NORTH 18TH STREET, SUITE 1600
PHILADELPHIA, PENNSYLVANIA 19103
TAF/1856